

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

*This document relates to:*

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**PLAINTIFFS' OMNIBUS MOTION *IN LIMINE*  
AND MEMORANDUM IN SUPPORT**

September 25, 2019

## TABLE OF CONTENTS

*Page*

Table of Authorities.....	v
GENERAL LIMINE REQUESTS (NON-CASE-SPECIFIC).....	1
1. Any reference to the parties’ attorneys’ fee arrangement or how litigation expenses are paid, or how much those expenses are, in connection with this or any similar litigation.....	1
2. Any reference to how, when, or under what circumstances, the parties selected or hired their attorneys, or to any referral arrangements or other counsel the parties may have retained or consulted beyond their current counsel.....	2
3. Any reference to whether counsel generally represents plaintiffs or defendants, what type of law they practice, and how they obtain clients. ....	2
4. Any reference suggesting or in any way reflecting the financial status or resources of any of the attorneys representing the parties, or those attorneys’ law firms, or any of those attorneys’ other businesses or cases. ....	3
5. Any references to the accommodations of, or the use of private aircraft for transportation by, any witnesses, parties, or counsel. ....	3
6. Any comment or reference to philanthropy or good deeds or acts carried out by the parties or their employees unrelated to opioid addiction prevention ( <i>e.g., references to community service or charity work, or charitable donations made by Defendants or any of their employees, statements that Defendants are “good corporate citizens,” etc.</i> ).....	4
7. Any reference to any alleged malpractice claims involving the parties’ designated experts.....	5
8. Any reference to experts not testifying in this litigation, experts retained in other cases, experts that were de-designated in this case, or any scientific or other discipline(s) for which no expert has been designated by the opposing party. ....	6
9. Use of any deposition video or associated technology that alters the appearance of what was displayed at the deposition, including but not limited to, the use of “highlighting,” enlarging, or otherwise emphasizing documents or portions of documents, unless the emphasis was done during the deposition and is part of the deposition video record. ....	6
10. Any reference to unrelated personal matters of a party’s expert or the expert’s family, such as divorce proceedings, employment or other disputes, and any other unrelated matters.....	8

11.	Any reference to the filing of the parties' motions <i>in limine</i> , the contents thereof, or other such motions to exclude evidence and their contents, and any agreements or proceedings in connection with this motion or reference to any such matter. ....	8
12.	Any suggestion or reference that an award of punitive damages is unconstitutional or illegal. ....	9
GENERAL LIMINE REQUESTS (CASE-SPECIFIC) .....		10
13.	Any argument or suggestion that the Controlled Substances Act and its implementing regulations do not impose, or have not always imposed, on registrants an identification duty, reporting duty, and no-shipping duty with respect to suspicious orders. ....	10
14.	Any reference that tort laws frustrate the FDA's or DEA's regulatory policies, or to the potential impact on pharmaceutical companies, the FDA, or the DEA, if any, of permitting tort claims to be asserted or of allowing a plaintiff to prevail. ....	11
15.	Any reference to the DEA "approving" or "endorsing" a particular Defendant's SOM program. ....	12
16.	Any suggestion or argument that the DEA's failure to sanction or initiate enforcement actions against a particular Defendant demonstrates a determination by the DEA that the Defendant complied with the CSA or its implementing regulations, or gives rise to a presumption that Defendants complied with same. ....	20
17.	Any suggestion or argument that the FDA's failure to sanction or initiate enforcement actions against a particular Defendant demonstrates a determination by the FDA that the Defendant complied with the Federal Food, Drug, and Cosmetic Act or FDA regulations, or gives rise to a presumption that Defendants complied with same. ....	20
18.	Any reference that any award of damages will adversely affect the ability of any member of the jury to purchase, or have available medications in the future, or affect the cost thereof, or have an adverse effect on the drugs or health products available to individuals or industries in the United States or elsewhere ( <i>e.g., argument or testimony that if Plaintiffs are awarded damages, the cost of medicines or medical care will increase, or that medications will no longer be available.</i> ). ....	22
19.	Any suggestion or indication that a judgment in this case will have an adverse effect on the finances or ability of Defendants to compete in the marketplace, or that it may negatively affect the economy or lead to layoffs ( <i>e.g., any argument or testimony that a judgment in this or any other case might force the company to lay off employees, or cut back on its business, or affect the local or other economy</i> ). ....	23
20.	Any reference that a verdict for Plaintiffs will adversely impact pharmaceutical manufacturers' incentive or ability to develop new drugs. ....	24
21.	Any reference to or suggestion that Defendants and the pharmaceutical industry have to factor in the overall cost of lawsuits when determining the cost of their products to the public ( <i>e.g., argument or testimony that lawsuits and claims force companies to charge more for their products</i> ). ....	25

22.	Any reference to deposition or trial testimony derived from witnesses produced only in litigation in which Plaintiffs did not participate, other than testimony that has been produced to Plaintiffs during discovery in this MDL that may be offered for impeachment purposes. ....	25
23.	Any argument or suggestion that the “learned intermediary” doctrine limits the liability of any Defendant or absolves any Defendant from liability. ....	27
24.	Any reference to, or evidence of, any alleged “failure to mitigate” by Plaintiffs. ....	29
PLAINTIFF-SPECIFIC LIMINE REQUESTS .....		31
25.	Any reference to, or evidence of, the identities of any children, including but not limited to children in child protective custody. ....	31
26.	Any reference to, or evidence of, any individually identifiable health information or medical records related to any individual patients, including but not limited to information or records that identifies babies with neonatal abstinence syndrome or persons with opioid use disorder. ....	31
27.	Any reference to, or evidence of, the identity of any undercover law enforcement personnel who may be called to testify at trial. ....	34
28.	Any reference to deaths of individuals while in the Cuyahoga County Jail or in the custody of the Cuyahoga County Sheriff’s Office, and any reference to the U.S. Marshalls Service report on jails. ....	36
29.	Any reference to or allegation of current or former government corruption in Cuyahoga County. ....	36
30.	Any reference to grand jury testimony or proceedings involving Cuyahoga County. ....	37
31.	Any reference to recent investigations or subpoenas involving Cuyahoga County. ....	37
32.	Any reference to the indictment of Ken Mills, former director of Cuyahoga County jails. ....	38
33.	Any reference to any investigations of former Cuyahoga County Sheriff Pinkney or the Cuyahoga County Sheriff’s Office. ....	38
34.	Any reference to any “podcast” or other media coverage regarding Cuyahoga County courts. ....	38
35.	Any reference to any investigation regarding the death of Aniya Day Garrett. ....	39
36.	Any reference to or allegation of current or former government corruption in Summit County. ....	39

37. Any reference to deaths of individuals while in the Summit County Jail or in the custody of the Summit County Sheriff's Office.....	40
---	----

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>CASES</b>	
<i>Abercrombie &amp; Fitch Stores, Inc. v. Am. Com. Const., Inc.</i> , 2:08-CV-925, 2010 WL 1640883 (S.D. Ohio Apr. 22, 2010) .....	15, 16
<i>ADR Tr. Corp. v. Cheshire Mgt. Co., Inc.</i> , 842 F. Supp. 295 (W.D. Tenn. 1992) .....	16
<i>Ansell v. Green Acres Contracting Co.</i> , 347 F.3d 515 (3rd Cir. 2003) .....	4
<i>Ayala v. Speckard</i> , 131 F.3d 62 (2d Cir. 1997) .....	35
<i>Bausch &amp; Lomb Inc. v. Vitamin Health, Inc.</i> , 13-CV-6498, 2016 WL 3742156 (W.D.N.Y. July 7, 2016) .....	11
<i>BMW of North America, Inc. v. Gore</i> , 517 U.S. 559 (1996) .....	9
<i>BP Exploration &amp; Oil Co. v. Maint. Servs., Inc.</i> , 313 F.3d 936 (6th Cir. 2002) .....	29
<i>Bryan v. U.S.</i> , 524 U.S. 184 (1998) .....	17
<i>Chicago Title Ins. Co. v. Huntington Natl. Bank</i> , 1999-Ohio-62, 719 N.E.2d 955 (Ohio 1999) .....	29
<i>Complaint of Paducah Towing Co., Inc.</i> , 692 F.2d 412 (6th Cir. 1982) .....	26, 27
<i>Crothers v. Pioneer Mut. Ins. Co.</i> , 13511, 1993 WL 405449 (Ohio App. 2d Dist. Oct. 12, 1993) .....	9
<i>Cuadra v. Univision Commun., Inc.</i> , CV 09-4946(JLL), 2013 WL 12153536 (D.N.J. Jan. 14, 2013) .....	20
<i>D &amp; S Remodelers, Inc. v. Wright Natl. Flood Ins. Services, LLC</i> , 725 Fed. Appx. 350 (6th Cir. 2018) .....	16
<i>Delaware v. Van Arsdall</i> , 475 U.S. 673, 106 S. Ct. 1431 (1986) .....	35
<i>Doe v. Claiborne County</i> , 103 F.3d 495 (6th Cir. 1996) .....	37, 39, 40

<i>Farmers Home Admin. v. Call</i> , 145 F.3d 1331, 1998 WL 246038 (6th Cir. 1998) .....	16
<i>Fisher v. Peters</i> , 249 F.3d 433 (6th Cir. 2001).....	15, 21
<i>Georges v. Novartis Pharm. Corp.</i> , CV 06-05207, 2013 WL 5217198 (C.D. Cal. Apr. 4, 2013) .....	11, 12, 21
<i>Green v. U.S.</i> , 8 F. Supp. 2d 983 (W.D. Mich. 1998) .....	15
<i>Grizzle v. Gen. Growth Properties, Inc.</i> , CIV-10-388-C, 2011 WL 7268176 (W.D. Okla. Oct. 12, 2011).....	8
<i>Guthrie v. Ball</i> , No. 1:11-CV-333-SKL, 2014 WL 11581410 (E.D. Tenn. Oct. 10, 2014) .....	26
<i>Hawthorne Educational Services, Inc. v. Friedman</i> , 225 F.3d 658, 2000 WL 799339 (6th Cir. 2000) .....	5, 8
<i>Heckler v. Community Health Services of Cranford County, Inc.</i> , 467 U.S. 51 (1984).....	14, 15, 16
<i>Highland Park Patient Collective, Inc. v. U.S. Dept of J.</i> , CV1209958RGKFFMX, 2013 WL 12142958 (C.D. Cal. Mar. 20, 2013).....	15
<i>In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liab. Litig.</i> , MDL 3:11-MD-2244-K, 2017 WL 9807464 (N.D. Tex. Sept. 19, 2017).....	passim
<i>In re Grand Jury Proceedings</i> , 841 F.2d 1264 (6 <sup>th</sup> Cir. 1988) .....	37
<i>In re Levaquin Products Liab. Litig.</i> , CIV. 08-5742 JRT, 2011 WL 6888533 (D. Minn. Dec. 29, 2011) .....	10, 23, 24, 25
<i>In re Polyurethane Foam Antitrust Litig. Direct Purchaser Class</i> , 1:10 MD 2196, 2015 WL 12747961 (N.D. Ohio Mar. 6, 2015).....	27
<i>In re Vioxx Products Liab. Litig.</i> , MDL 1657, 2005 WL 3164251 (E.D. La. Nov. 18, 2005) .....	passim
<i>In re Welding Fume Products Liab. Litig.</i> , 1:03-CV-17000, 2010 WL 7699456 (N.D. Ohio June 4, 2010) .....	passim
<i>In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and PMF Products Liab. Litig.</i> , 3:09-CV-10012-DRH, 2011 WL 6740391 (S.D. Ill. Dec. 22, 2011) .....	passim

<i>In re: Tylenol (Acetaminophen) Mktg.</i> , 2436, 2016 WL 3125428 (E.D. Pa. June 3, 2016).....	passim
<i>Indiana Ins. Co. v. Gen. Elec. Co.</i> , 326 F. Supp. 2d 844 (N.D. Ohio 2004) .....	1
<i>Johnson v. Univ. Hosps. of Cleveland</i> , 540 N.E.2d 1370 (Ohio 1989).....	29, 30
<i>Jordan v. John Soliday Fin. Group, LLC</i> , 1:09CV0707, 2010 WL 4281807 (N.D. Ohio Oct. 20, 2010) .....	1
<i>Kirksey v. Schindler Elevator Corp.</i> , CV 15-0115-WS-N, 2016 WL 7116223 (S.D. Ala. Dec. 6, 2016) .....	9
<i>Levinson v. Westport Nat. Bank</i> , 3:09-CV-1955 VLB, 2013 WL 2181042 (D. Conn. May 20, 2013).....	5
<i>Louzon v. Ford Motor Co.</i> , 718 F.3d 556 (6th Cir. 2013).....	1
<i>Magadia v. Wal-Mart Associates, Inc.</i> , 17-CV-00062-LHK, 2018 WL 6003376 (N.D. Cal. Nov. 15, 2018).....	11
<i>Masters Pharm., Inc. v. Drug Enf't Administration</i> , 861 F.3d 206 (D.C. Cir. 2017) .....	22
<i>McFadden v. U.S.</i> , 135 S. Ct. 2298 (2015) .....	18
<i>Michigan Exp., Inc. v. U.S.</i> , 374 F.3d 424 (6th Cir. 2004).....	13, 14, 15
<i>Moran Mar. Associates v. U.S. Coast Guard</i> , 526 F. Supp. 335 (D.D.C. 1981), <i>aff'd sub nom. Moran Mar. Associates Am. Waterways</i> <i>Operators, Inc. v. U.S. Coast Guard</i> , 679 F.2d 261 (D.C. Cir. 1982).....	22
<i>Murphy v. Owens-Illinois, Inc.</i> , 779 F.2d 340 (6th Cir. 1985).....	27
<i>Nienwiadomski v. U.S.</i> , 159 F.2d 683 (6th Cir. 1947).....	13, 14
<i>Niver v. Travelers Indem. Co. of Illinois</i> , 433 F. Supp. 2d 968 (N.D. Iowa 2006) .....	4
<i>Off. of Personnel Mgt. v. Richmond</i> , 496 U.S. 414 (1990).....	13, 14, 15



<i>P. Shrimp Co. v. U.S., Dept. of Transp.</i> , 375 F. Supp. 1036 (W.D. Wash. 1974).....	14
<i>Parrish v. Machlan</i> , 722 N.E.2d 529 (Ohio App. 1 Dist. 1997) .....	29
<i>Positive Ions, Inc. v. Ion Media Networks, Inc.</i> , CV064296ABCFFMX, 2007 WL 9701734 (C.D. Cal. Nov. 7, 2007) .....	2
<i>Premo v. U.S.</i> , 599 F.3d 540 (6th Cir. 2010).....	13, 14, 15
<i>Preston v. Murty</i> , 512 N.E.2d 1174 (Ohio 1987).....	9
<i>Rodriguez v. Miller</i> , 537 F.3d 102 (2d Cir. 2008) .....	35
<i>Sadler v. Advanced Bionics, LLC</i> , No. 3:11-CV-00450-TBR, 2013 WL 1385386 (W.D. Ky. Apr. 3, 2013).....	4, 24
<i>Seley v. G.D. Searle &amp; Co.</i> , 423 N.E.2d 831 (Ohio 1981) .....	27
<i>St.-Gobain Autover USA, Inc. v. Xinyi Glass N.A., Inc.</i> , 1:06CV2781, 2009 WL 10689369 (N.D. Ohio Oct. 23, 2009) .....	10, 11
<i>State Farm Mut. Auto. Ins. Co. v. Campbell</i> , 538 U.S. 408 (2003).....	9
<i>U.S. ex rel. Garrison v. Crown Roofing Services, Inc.</i> , CIV.A. H-07-1018, 2011 WL 4914971 (S.D. Tex. Oct. 14, 2011).....	31
<i>U.S. ex rel. Kiro v. Jiaberb, Inc.</i> , CV 14-2484-RSWL-PLAX, 2019 WL 2869186 (C.D. Cal. July 3, 2019) .....	4
<i>U.S. ex rel. Monahan v. Robert Wood Johnson U. Hosp. at Hamilton</i> , CIV. A. 02-5702 JAG, 2009 WL 4576097 (D.N.J. Dec. 1, 2009) .....	31
<i>U.S. v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device</i> , 799 F. Supp. 1275 (D.P.R. 1992) .....	14, 22
<i>U.S. v. Aging Care Home Health, Inc.</i> , CIVA 3-02-2199, 2006 WL 2915674 (W.D. La. Oct. 6, 2006).....	31
<i>U.S. v. Ansaldi</i> , 372 F.3d 118 (2d Cir. 2004) .....	18

<i>U.S. v. Articles of Drug . . . Hormonin</i> , 498 F. Supp. 424 (D.N.J. 1980), <i>aff'd sub nom. App. of Carnrick Laboratories, Inc.</i> , 672 F.2d 902 (3d Cir. 1981), <i>aff'd sub nom. U.S. v. Articles of Drug</i> , 672 F.2d 904 (3d Cir. 1981).....	13, 14, 17
<i>U.S. v. Associates in Eye Care, P.S.C.</i> , 13-CV-27-GFVT, 2014 WL 12606508 (E.D. Ky. Nov. 14, 2014) .....	30, 31
<i>U.S. v. Barnes</i> , 677 Fed. Appx. 271 (6th Cir. 2017) .....	18, 19
<i>U.S. v. City of Menominee, Mich.</i> , 727 F. Supp. 1110 (W.D. Mich. 1989) .....	13, 16, 21, 22
<i>U.S. v. City of Toledo</i> , 867 F. Supp. 603 (N.D. Ohio 1994).....	21
<i>U.S. v. Fuller</i> , 162 F.3d 256 (4th Cir. 1998).....	17, 18
<i>U.S. v. Hayes</i> , 219 Fed. Appx. 114 (3d Cir. 2007) .....	4
<i>U.S. v. Hoyt</i> , 2:14CR00001, 2014 WL 5023093 (W.D. Va. Oct. 8, 2014) .....	18, 19, 21
<i>U.S. v. Scarmazzzo</i> , 554 F. Supp. 2d 1102 (E.D. Cal. 2008), <i>aff'd sub nom. U.S. v. Montes</i> , 421 Fed. Appx. 670 (9th Cir. 2011).....	17, 18
<i>U.S. v. Tobin</i> , 676 F.3d 1264 (11th Cir. 2012) .....	18, 19
<i>U.S. v. Walsh</i> , 654 Fed. Appx. 689 (6th Cir. 2016) .....	1, 18
<i>United States v. Maso</i> , No. 07-10858, 2007 WL 3121986 (11th Cir. 2007) (per curiam) .....	35
<i>United States v. United Techs. Corp.</i> , 950 F. Supp.2d 949 (S.D. Ohio 2013).....	30
<i>Walker ex rel. his Ct. Appointed Curator v. United Healthcare of Hardin, Inc.</i> , 3:07-00067-JHM, 2010 WL 3092648 (W.D. Ky. Aug. 6, 2010) .....	19
<i>Washington Tour Guides Ass'n v. Natl. Park Serv.</i> , 808 F. Supp. 877 (D.D.C. 1992) .....	13, 22
<i>Wilber Nat. Bank of Oneonta, N.Y., v. U.S.</i> , 294 U.S. 120 (1935).....	13, 16

<i>Williamson v. Haviland</i> , 1:04 CV 629, 2006 WL 287991 (N.D. Ohio Feb. 6, 2006) .....	5, 8
<i>Wilson v. Maricopa County</i> , CV-04-2873 PHXDGC, 2007 WL 686726 (D. Ariz. Mar. 2, 2007) .....	8
<i>Wilson v Sheldon</i> , 874 F.3d 470 (6 <sup>th</sup> Cir. 2017) .....	37
<i>Wright v. Columbia Sussex Corp.</i> , 3:06-CV-190, 2008 WL 972699 (E.D. Tenn. Apr. 7, 2008) .....	19, 20

## STATUTES

21 U.S.C. § 841 .....	17, 18, 19
21 U.S.C. § 843 .....	17
42 U.S.C. § 5106a .....	32
42 U.S.C. § 290dd .....	32
OHIO ADMIN. CODE 5101:2-33-21 .....	32
OHIO ADMIN. CODE 5101:2-33-23 .....	32
OHIO ADMIN. CODE 5101:2-48-23 .....	32
OHIO REV. CODE § 2307.76.....	27
OHIO REV. CODE § 2151.142 .....	32
OHIO REV. CODE § 2151.421 .....	32
OHIO REV. CODE § 3107.17.....	32
OHIO REV. CODE § 5101.29.....	32
OHIO REV. CODE § 5101.131 .....	32
OHIO REV. CODE § 5153.17.....	32

## OTHER AUTHORITIES

34 CFR § 99.31.....	32
42 C.F.R. Part 2.....	33
45 C.F.R. § 164.514.....	33, 34

45 C.F.R. § 164.502.....	33
FED. R. CIV. P. 32.....	26
FED. R. CRIM. P. 6.....	37
FED. R. EVID. 401 .....	passim
FED. R. EVID. 402 .....	passim
FED. R. EVID. 403 .....	passim
FED. R. EVID. 404 .....	4, 5
FED. R. EVID. 611 .....	5, 7, 8
FED. R. EVID. 804 .....	26
<a href="https://serialpodcast.org/">https://serialpodcast.org/</a> .....	38
RESTATEMENT (SECOND) OF TORTS § 918.....	30

Before the voir dire examination of the jury panel, Plaintiffs make this motion *in limine*. Plaintiffs seek to exclude matters that are inadmissible, irrelevant, or unduly prejudicial to the material issues in this case. If Defendants inject these matters in this case through a party, an attorney, or a witness, Defendants will cause irreparable harm to Plaintiffs' cases that no jury instruction would cure. If any of these matters are directly or indirectly brought to the attention of the jury, Plaintiffs will be compelled to move for a mistrial. In an effort to avoid prejudice and a possible mistrial, and to avoid unnecessary trial interruptions, Plaintiffs make this motion *in limine*. See *Louzon v. Ford Motor Co.*, 718 F.3d 556, 561 (6th Cir. 2013) (" '[A] motion *in limine* is designed to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions.' ") (citation omitted); *U.S. v. Walsh*, 654 Fed. Appx. 689, 693 (6th Cir. 2016) (unpublished) (same); *Indiana Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004) ("Motions in limine are generally used to ensure evenhanded and expeditious management of trials by eliminating evidence that is clearly inadmissible for any purpose."); *Jordan v. John Soliday Fin. Group, LLC*, 1:09CV0707, 2010 WL 4281807, at \*1 (N.D. Ohio Oct. 20, 2010) ("A motion in limine may also be used to prevent a jury from exposure to prejudicial evidence.").

Plaintiffs ask the Court to prohibit Defendants, and their counsel and witnesses, from offering any of the following matters without first asking for a ruling from the Court, outside the jury's presence, on the admissibility of the matter.

**GENERAL LIMINE REQUESTS (NON-CASE-SPECIFIC)**

1. **Any reference to the parties' attorneys' fee arrangement or how litigation expenses are paid, or how much those expenses are, in connection with this or any similar litigation.**

Any evidence of or reference to the parties' attorneys' fee arrangements, or how litigation expenses are paid or the amount of those expenses, in connection with this or any similar litigation is not relevant to any issue to be decided in this case. Defendants' sole purpose in trying to elicit such information would be to potentially prejudice the jury. Such evidence should be excluded under Rules 401, 402 and 403. See *In re Welding Fume Products Liab. Litig.*, 1:03-CV-17000, 2010 WL

7699456, at \*78 (N.D. Ohio June 4, 2010) (granting plaintiff's motion to exclude references that impugn the motives of counsel or denigrate the basis for fees, including "any observation that plaintiffs' counsel get paid on a contingent basis"); *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liab. Litig.*, MDL 3:11-MD-2244-K, 2017 WL 9807464, at \*3 (N.D. Tex. Sept. 19, 2017) (granting similar motion *in limine*); *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and PMF Products Liab. Litig.*, 3:09-CV-10012-DRH, 2011 WL 6740391, at \*16 (S.D. Ill. Dec. 22, 2011) (same); *Positive Ions, Inc. v. Ion Media Networks, Inc.*, CV064296ABCFFMX, 2007 WL 9701734, at \*2 (C.D. Cal. Nov. 7, 2007) (granting plaintiff's motion *in limine* to exclude all evidence and reference to contingency fee agreements, noting "proof of contingency fee arrangements carries with it too high a risk of unfair prejudice, confusion and the potential to mislead the jury").

**2. Any reference to how, when, or under what circumstances, the parties selected or hired their attorneys, or to any referral arrangements or other counsel the parties may have retained or consulted beyond their current counsel.**

The circumstances under which and the reasons why any client seeks legal representation are not relevant to any issue to be decided by the jury in any case. Defendants should be precluded under Rules 401, 402 and 403 from commenting on these matters. *See DePuy*, 2017 WL 9807464, at \*3 (granting similar motion *in limine*); *In re: Tylenol (Acetaminophen) Mktg.*, 2436, 2016 WL 3125428, at \*5-6, \*17 (E.D. Pa. June 3, 2016) (granting similar motions *in limine* because such "evidence is irrelevant to the issues of this case and would be unduly prejudicial"); *Yasmin*, 2011 WL 6740391, at \*16 (granting motion *in limine* to exclude "[a]ny comment, evidence, testimony, or inference about how, when, or under what circumstances Plaintiff chose or employed any of her attorneys").

**3. Any reference to whether counsel generally represents plaintiffs or defendants, what type of law they practice, and how they obtain clients.**

Any evidence of or reference to the fact that Plaintiffs' attorneys primarily represent plaintiffs in lawsuits, specialize in personal injury or product liability litigation, advertise, seek to obtain clients in a manner different from that used by defense counsel, or routinely employ contingent fee arrangements, is not relevant to any issue to be decided in this case. Defendants' sole

purpose in trying to elicit such information would be to potentially prejudice the jury. Such evidence should be excluded under Rules 401, 402 and 403. *See Welding Fume*, 2010 WL 7699456, at \*78 (granting plaintiff's motion to exclude references that impugn the motives of counsel or denigrate the basis for fees, including "any observation that plaintiffs' counsel get paid on a contingent basis"); *DePuy*, 2017 WL 9807464, at \*2 (granting similar motion *in limine*); *In re Vioxx Products Liab. Litig.*, MDL 1657, 2005 WL 3164251, at \*1 (E.D. La. Nov. 18, 2005) (granting plaintiff's motion *in limine* to exclude "[a]ny reference that the [p]laintiff's attorneys specialize [in] representing plaintiffs in personal injury or products liability litigation").

**4. Any reference suggesting or in any way reflecting the financial status or resources of any of the attorneys representing the parties, or those attorneys' law firms, or any of those attorneys' other businesses or cases.**

Just as the circumstances under which, and the reasons why, any client seeks legal representation are not relevant to any issue to be decided by the jury in any case, so, too, are matters related to the financial status of the client's counsel. The only possible reason why Defendants would seek to comment on or introduce information about Plaintiffs' counsel's financial status, resources, other cases, or business interests would be to prejudice the jury. Such evidence should be excluded under Rules 401, 402 and 403. *See DePuy*, 2017 WL 9807464, at \*3 (granting similar motion *in limine*); *Tylenol*, 2016 WL 3125428, at \*6 (same).

**5. Any references to the accommodations of, or the use of private aircraft for transportation by, any witnesses, parties, or counsel.**

As with the discussion regarding MIL No. 4 above, the ownership or use of private aircraft by any witness, any party, or any lawyer for the parties, or the accommodations used by any witness, party, or lawyer for the parties, is not relevant to any issue in this case. The only purpose of this information would be to attempt to prejudice the jury against the parties or their lawyers, and potentially cause the jury to decide the case on improper grounds rather than the relevant, admissible evidence presented at trial. Such evidence should be excluded under Rules 401, 402 and 403. *See Welding Fume*, 2010 WL 7699456, at \*71 (granting plaintiff's motion to exclude evidence of

flying on private airplanes); *DePuy*, 2017 WL 9807464, at \*3 (granting similar motion *in limine*); *Tylenol*, 2016 WL 3125428, at \*6 (same).

**6. Any comment or reference to philanthropy or good deeds or acts carried out by the parties or their employees unrelated to opioid addiction prevention (e.g., references to community service or charity work, or charitable donations made by Defendants or any of their employees, statements that Defendants are “good corporate citizens,” etc.).**

With one limited exception,<sup>1</sup> Defendants should not be allowed to argue or suggest at trial that Defendants are “good” (including statements such that Defendants are “good neighbors,” “good corporate citizens,” or “employ a lot of people”) or benevolent companies that benefit society, donate to worthy causes, or manufacture and market life-saving drugs or products that improve people’s lives. Any such evidence, argument, or implication that is unrelated to opioid addiction prevention is not relevant to any fact at issue in this matter and would constitute inadmissible character evidence used to prove conduct in conformity therewith.<sup>2</sup> See *Sadler v. Advanced Bionics, LLC*, No. 3:11-CV-00450-TBR, 2013 WL 1385386, at \*2 (W.D. Ky. Apr. 3, 2013) (excluding references to philanthropic good deeds and other bolstering activity attributable to manufacturing company and its founder as irrelevant in a products liability suit regarding cochlear implants).<sup>3</sup>

---

<sup>1</sup> Plaintiffs’ *limine* request does not seek to preclude evidence of Defendants’ work related to opioid addiction prevention, although Plaintiffs reserve the right to object to such evidence at trial.

<sup>2</sup> Evidence of prior or subsequent “good acts” is not permitted under Federal Rule of Evidence 404(b). While Rule 404(b) is most commonly utilized to exclude “bad acts,” it also applies to “good acts,” in what is commonly referred to as a “reverse 404(b).” See *U.S. v. Hayes*, 219 Fed. Appx. 114, 116 (3d Cir. 2007) (unpublished) (“The rule prohibits evidence of good acts if that evidence is used to establish the defendant’s good character.”); *Ansell v. Green Acres Contracting Co.*, 347 F.3d 515, 520 (3rd Cir. 2003).

<sup>3</sup> See also *Niver v. Travelers Indem. Co. of Illinois*, 433 F. Supp. 2d 968, 994-95, 1000-01 (N.D. Iowa 2006) (“The court finds that unrelated ‘good acts’ simply are not relevant pursuant to Rule 401, and therefore, not admissible pursuant to Rule 402....”); *U.S. ex rel. Kiro v. Jiaberh, Inc.*, CV 14-2484-RSWL-PLAX, 2019 WL 2869186, at \*4 (C.D. Cal. July 3, 2019) (“Relator’s MIL #7 requests that Defendant be precluded from introducing evidence regarding supposed ‘good acts,’ such as charitable contributions or community service performed by Defendant or its employees. The Court agrees and finds that any such evidence of ‘good acts’ is irrelevant to the alleged scheme of whether Defendant knowingly submitted false claims to CBP to receive lower duties.”); *Tylenol*, 2016 WL 3125428, at \*8, \*11 (granting plaintiff’s motion *in limine* to exclude evidence or argument concerning the societal good defendants perform by manufacturing (footnote continues on next page)



For these reasons, Defendants should be precluded from offering evidence or argument regarding the philanthropy or good deeds of Defendants or their employees that are unrelated to opioid addiction prevention.

**7. Any reference to any alleged malpractice claims involving the parties' designated experts.**

The parties should be precluded from offering evidence or mentioning any alleged claims of malpractice by any of the experts designated in this case. Their conduct is not at issue. *See Hawthorne Educational Services, Inc. v. Friedman*, 225 F.3d 658, 2000 WL 799339, at \*3 (6th Cir. 2000) (unpublished) ("It is generally true that extrinsic evidence may not be admitted to impeach a witness on a collateral issue."); *Williamson v. Haviland*, 1:04 CV 629, 2006 WL 287991, at \*7 (N.D. Ohio Feb. 6, 2006) ("A witness may not be impeached by evidence that merely contradicts her testimony on collateral matters. The Sixth Circuit is in conformity with the Ohio Supreme Court.") (internal citation omitted). Consequently, any mention of or reference to any alleged malpractice claims should be precluded because (1) it is not relevant to any issue to be decided in these cases (Rules 401, 402); (2) the probative value is substantially outweighed by the risk of unfair prejudice, confusing the issues, and misleading the jury (Rule 403); and (3) it exceeds the scope of permissible cross-examination under Rule 611(b). *See DePuy*, 2017 WL 9807464, at \*3 (granting identical motion *in limine*).

---

other drugs or products; "Evidence of the defendants' 'good corporate character' is not admissible in the defendants' case-in-chief under Rule 404(a). Evidence of the defendants' charitable work would have no probative value."); *Levinson v. Westport Nat. Bank*, 3:09-CV-1955 VLB, 2013 WL 2181042, at \*4 (D. Conn. May 20, 2013) (granting plaintiff's motion *in limine* "to exclude evidence relating to the Bank's community involvement such as its charitable contributions and its practice of lending to local businesses . . . as such evidence is not relevant to any claim or defense at issue"); *Yasmin*, 2011 WL 6740391, at \*16 ("Bayer is not allowed to argue to the jury, even in the punitive damages phase, that it is the company that introduced a drug or drugs that greatly benefited society in an effort to have the jury overlook any wrong the jury might otherwise find with the contraceptive at issue here."); *Vioxx*, 2005 WL 3164251, at \*1 (granting plaintiff's motion *in limine* to exclude any evidence or testimony as to the defendant's good reputation and other good acts pursuant to Rule 401).

8. **Any reference to experts not testifying in this litigation, experts retained in other cases, experts that were de-designated in this case, or any scientific or other discipline(s) for which no expert has been designated by the opposing party.**

The parties should be precluded from referring to experts retained in other cases or experts previously designated but now de-designated, and from referring to or commentary that a party has not designated or brought to trial an expert in any particular scientific or other discipline. The fact that Plaintiffs at this trial have chosen different experts than were selected for other related litigations is not probative of any issue in the case: it does not make the existence of any fact of consequence to the action more or less probable. FED. R. EVID. 401. Nor is it relevant that a particular scientific or other discipline is not represented by an expert on behalf of Plaintiffs at trial. In other opioid litigation, expert witnesses were selected by counsel. The selection may reflect the trial strategy of the lawyers, but says nothing about the underlying facts of any of the cases. Its only effect, and its only purpose, are jury confusion and prejudice. Such evidence should therefore be excluded under Rules 402 and 403.

Additionally, Defendants may wish to suggest that the jury should draw inferences that the previous experts (both not designated and de-designated) were unwilling or unable to provide useful expert opinions in this case, or that Plaintiffs were unable to find an expert in a particular scientific or other discipline that would be willing to testify at trial. There is no factual basis or foundation for such inferences, and Plaintiffs could not respond to the innuendo without introducing collateral evidence about the trial strategy process. Any slight probative value of any such references and commentary would be substantially outweighed by the danger of unfair prejudice and confusion of the issues. Accordingly, such potential references or commentary by any party should be precluded.

9. **Use of any deposition video or associated technology that alters the appearance of what was displayed at the deposition, including but not limited to, the use of “highlighting,” enlarging, or otherwise emphasizing documents or portions of documents, unless the emphasis was done during the deposition and is part of the deposition video record.**

It is expected that Defendants will seek to impermissibly draw attention to documents and testimony at trial that was not focused upon during the deposition. For example, Defendants may

attempt to highlight documents, enlarge exhibits or otherwise emphasize documents or portions of documents while playing videotaped depositions to the jury. Plaintiffs seek to prohibit Defendants' lawyers from emphasizing any part of the deposition or exhibits referenced in the deposition unless the emphasis was performed at the time of the deposition.

It would be fundamentally unfair to enlarge, underline, highlight or otherwise emphasize documents for the first time at trial that had been presented in deposition without emphasis and without providing the witness and opposing counsel advance notice of how the jury will perceive the witness' testimony—and without affording the witness and opposing counsel an opportunity to rebut the emphasis made by the questioning attorney. A large number of depositions in this case have been videotaped with the expectation that the witness will appear via videotaped deposition rather than being brought live to testify. Plaintiffs' counsel has enlarged, highlighted and emphasized documents with witnesses during the deposition, who then have the opportunity to react to and testify according to counsel's emphasis. Defense counsel has been afforded the fair opportunity to examine witnesses in response. Defendants seek to have their cake and eat it, too, by choosing not to highlight or emphasize documents and evidence during depositions, taking their chances that they will be able to do so at trial and without providing the same fair notice to Plaintiffs and their counsel so they may react and address the testimony.

If Defendants are permitted to, in effect, modify the deposition from how it was contemporaneously taken, witness testimony and documents will be unfairly emphasized without prior notice to the witness or counsel, depriving Plaintiffs of the ability to fairly re-cross or re-direct the witness. The Court has the broad discretion to limit counsel from using misleading and unfair tactics in presenting evidence and testimony. FED. R. EVID. 611. Accordingly, Plaintiffs respectfully request that the Court prohibit Defendants from emphasizing any exhibit referenced in a deposition unless the emphasis was performed at the time of the deposition. *See DePuy*, 2017 WL 9807464, at \*4 (granting identical motion *in limine*).

**10. Any reference to unrelated personal matters of a party's expert or the expert's family, such as divorce proceedings, employment or other disputes, and any other unrelated matters.**

With regard to any expert witnesses called to testify at the upcoming trial, cross-examination should be limited to “the subject matter of the direct examination and matters affecting the witness’s credibility.” FED. R. EVID. 611(b). The parties should be precluded from cross-examining any expert on personal matters unrelated to their testimony in this case, including but not limited to divorce proceedings, employment or other legal disputes, and any other unrelated matters, because such matters are irrelevant and collateral to the present case. *See Hawthorne*, 2000 WL 799339, at \*3 (“It is generally true that extrinsic evidence may not be admitted to impeach a witness on a collateral issue.”); *Williamson*, 2006 WL 287991, at \*7 (“A witness may not be impeached by evidence that merely contradicts her testimony on collateral matters. The Sixth Circuit is in conformity with the Ohio Supreme Court.”) (internal citation omitted).

The parties should be precluded from cross-examination on unrelated matters because (1) they are not relevant to any issue to be decided in these cases (Rules 401, 402); (2) their probative value is substantially outweighed by the risk of unfair prejudice, confusing the issues, and misleading the jury (Rule 403); and (3) they exceed the scope of permissible cross-examination under Rule 611(b). *See DePuy*, 2017 WL 9807464, at \*4 (granting similar motion *in limine*); *Grizzle v. Gen. Growth Properties, Inc.*, CIV-10-388-C, 2011 WL 7268176, at \*3 (W.D. Okla. Oct. 12, 2011) (excluding any evidence of expert’s personal legal disputes as irrelevant to the subject of her expert testimony); *Wilson v. Maricopa County*, CV-04-2873 PHXDGC, 2007 WL 686726, at \*11 (D. Ariz. Mar. 2, 2007) (granting plaintiff’s motion *in limine* to exclude evidence regarding prior sexual harassment allegation against plaintiff’s expert).

**11. Any reference to the filing of the parties’ motions *in limine*, the contents thereof, or other such motions to exclude evidence and their contents, and any agreements or proceedings in connection with this motion or reference to any such matter.**

Both Plaintiffs and Defendants will be asking this Court to exclude certain matters that are inadmissible, irrelevant, or prejudicial to the material issues in this case. There is no reasonable

reason for the jury to be made aware of the filing of any of these motions, or their contents. Such evidence is not relevant to any issue to be decided in this case, and the probative value of such evidence is substantially outweighed by the risk of unfair prejudice, confusing the issues, and misleading the jury. *See Welding Fume*, 2010 WL 7699456, at \*78 (granting motions to exclude evidence of the parties' litigation documents because "this evidence does not help to establish any issue at trial"); *Kirksey v. Schindler Elevator Corp.*, CV 15-0115-WS-N, 2016 WL 7116223, at \*18 (S.D. Ala. Dec. 6, 2016) ("The Court does not perceive any valid reason why it would be appropriate to inform the jury about pretrial motion practice in this case, particularly as it relates to evidentiary matters or categories of arguments and information that the jury will or will not be allowed to receive[.]").

**12. Any suggestion or reference that an award of punitive damages is unconstitutional or illegal.**

Ohio recognizes that a court may award punitive damages in certain circumstances. *See, e.g., Preston v. Murty*, 512 N.E.2d 1174, 1175 (Ohio 1987) ("Ohio courts, since as early as 1859, have allowed punitive damages to be awarded in tort actions which involve fraud, malice, or insult."); *Crothers v. Pioneer Mut. Ins. Co.*, 13511, 1993 WL 405449, at \*5 (Ohio App. 2d Dist. Oct. 12, 1993) (same). The Supreme Court has also recognized the availability of punitive damages (so long as the award does not violate due process). *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 568 (1996) ("Punitive damages may properly be imposed to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition."). In considering on appeal whether a punitive damages award violates due process, the Supreme Court has established three factors: (1) the degree of reprehensibility of the defendant's misconduct; (ii) the disparity between the harm (or potential harm) suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases. *Id.* at 574. Whether a particular punitive damage award violates due process is a question of law for the court, not a determination to be made by a jury. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003).

Accordingly, any argument that punitive damages are unconstitutional or illegal is not appropriate and should be excluded. *See Tylenol*, 2016 WL 3125428, at \*6 (granting similar motion *in limine*); *In re Levaquin Products Liab. Litig.*, CIV. 08-5742 JRT, 2011 WL 6888533, at \*1 (D. Minn. Dec. 29, 2011) (granting plaintiff's motion *in limine* to exclude "evidence that an award of punitive damages might be unconstitutional"); *Yasmin*, 2011 WL 6740391, at \*16 (granting similar motion *in limine*); *Vioxx*, 2005 WL 3164251, at \*1 (granting plaintiff's motion *in limine* to exclude "[a]ny reference that an award of punitive damages is unconstitutional, illegal, or not supported by law").

### **GENERAL LIMINE REQUESTS (CASE-SPECIFIC)**

- 13. Any argument or suggestion that the Controlled Substances Act and its implementing regulations do not impose, or have not always imposed, on registrants an identification duty, reporting duty, and no-shipping duty with respect to suspicious orders.**

On August 19, 2019, this Court granted Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties under the Controlled Substances Act. Dkt. #2483. In its Opinion, the Court held, as a matter of law, that registrants under the CSA are required to: (i) "design and operate a system to disclose to the registrant suspicious orders;" (ii) "inform the DEA of suspicious orders when discovered by the registrant[;]" and (iii) decline to ship suspicious orders unless and until, through due diligence, the registrant can determine the orders are not likely to be diverted into illegal channels. *Id.* at pp. 15, 18-19. In so holding, the Court "relie[d] simply on the language of the statute and regulations themselves, as interpreted by federal courts." *Id.* at p. 18 n.13. Accordingly, any argument or suggestion that CSA registrants do not owe these duties, or that they have not always owed these duties since the relevant portions of the CSA and its implementing regulations were enacted, would be contrary to this Court's rulings and should be excluded. *See St.-Gobain Autover USA, Inc. v. Xinyi Glass N.A., Inc.*, 1:06CV2781, 2009 WL 10689369, at \*9-10 (N.D. Ohio Oct. 23, 2009) (granting plaintiff's motion to preclude defendants "from offering at trial a definition for the claim term 'centering' that was previously rejected by the Court"; "Inasmuch as the Court's Memorandum Opinion on claim construction is the law of the case, the Court will not permit either

party to offer evidence that contradicts the Court’s ruling.”); *Magadia v. Wal-Mart Associates, Inc.*, 17-CV-00062-LHK, 2018 WL 6003376, at \*2 (N.D. Cal. Nov. 15, 2018) (granting plaintiff’s motion to exclude evidence or argument that contradicts the court’s prior rulings on summary judgment; “[T]he court has already ruled on these matters in its summary judgment orders. Thus, testimony on these issues would have no probative value, and would merely waste time.”) (internal citation omitted); *Bausch & Lomb Inc. v. Vitamin Health, Inc.*, 13-CV-6498, 2016 WL 3742156, at \*2 (W.D.N.Y. July 7, 2016) (holding defendant “shall not introduce evidence that conflicts with or disputes the Court’s previous rulings on claim construction or matters of law”).

**14. Any reference that tort laws frustrate the FDA’s or DEA’s regulatory policies, or to the potential impact on pharmaceutical companies, the FDA, or the DEA, if any, of permitting tort claims to be asserted or of allowing a plaintiff to prevail.**

The interaction between the types of claims asserted by Plaintiffs and the DEA’s or FDA’s regulation of controlled substances is a matter of law and public policy that is beyond the purview of the jury. The statutory framework for regulation of controlled substances permits the assertion of tort claims against pharmaceutical manufacturers, distributors, or pharmacies who manufacture, market, or distribute controlled substances that harm others. Dkt. #1025 at pp. 52-54; Dkt. #1203 at p. 2; Dkt. #2565. Any evidence or argument that Plaintiffs’ claims interfere with or impact the pharmaceutical industry, or the FDA’s or DEA’s regulation of the pharmaceutical industry, or that a judgment in this case will interfere with or impact the industry, the FDA, or the DEA, should be excluded because: (1) it would be an incorrect statement of the law and conflict with this Court’s prior rulings on preemption (*see* Dkt. # 2565; *supra* at MIL No. 13); (2) it is not relevant to any issue to be decided in these cases (Rules 401, 402); and (3) the probative value of such evidence is substantially outweighed by the risk of unfair prejudice, confusing the issues, and misleading the jury (Rule 403). *See Tylenol*, 2016 WL 3125428, at \*8 (granting plaintiff’s motion *in limine* to exclude evidence or argument that state tort law undercuts the FDA’s mission to provide only scientifically valid warnings); *Georges v. Novartis Pharm. Corp.*, CV 06-05207 SJO VBKX, 2013 WL 5217198, at \*5 (C.D. Cal. Apr. 4, 2013) (granting plaintiff’s motion *in limine* to preclude “evidence suggesting that



state tort law undercuts the FDA’s mission to provide only scientifically valid warnings” because “[t]his information [wa]s not relevant to any of the issues in the case and would mislead and distract the jury”); *Vioxx*, 2005 WL 3164251, at \*1 (granting plaintiff’s motions *in limine* to exclude “[a]ny reference that state products liability laws frustrate the FDA’s protective regime” and “[a]ny reference that this case or any Vioxx case may have a negative impact on Merck’s stock price or any other publicly traded pharmaceutical manufacturer”).

**15. Any reference to the DEA “approving” or “endorsing” a particular Defendant’s SOM program.**

In an effort to refute Plaintiffs’ claim that they failed to maintain effective controls against diversion in violation of the Controlled Substances Act and its implementing regulations (collectively, the “CSA”), some Defendants may try to argue that certain statements or communications made by individual DEA agents regarding a particular Defendant’s SOM program demonstrate or imply that the DEA “approved” or “endorsed” that SOM program. Evidence or argument of this nature is improper and inadmissible because its probative value, if any, is substantially outweighed by the risk of unfair prejudice, confusing the issues, and misleading the jury. FED. R. EVID. 403.

Plaintiffs allege that Defendants violated the CSA and that these violations form a basis of their public nuisance and RICO/OCPA claims. As noted above (*supra* at MIL No. 13), the scope of the duties imposed by the CSA is a legal question that the Court has already resolved on summary judgment. Dkt. #2483. Defendants should not be permitted to introduce any statements of individual DEA agents regarding the scope of the CSA that contradict this Court’s prior legal determinations. *See supra* at MIL No. 13.

Moreover, the statements of an individual DEA agent purporting to “approve” or “endorse” a particular Defendant’s SOM program are irrelevant to the ultimate issue of whether that Defendant complied with the CSA’s SOM requirements. *See* Dkt. #2545 at pp. 13-16. As a preliminary matter, the DEA has explicitly and repeatedly stated that it “*does not approve or otherwise endorse any specific system for reporting suspicious orders.*” Dkt. #1944-6 at p. 1 (emphasis added);



see also Dkt. #2557-1 at p. 1.<sup>4</sup> Thus, any statements by individual DEA agents to the contrary cannot be construed as official “approvals” or “endorsements” of the DEA. Moreover, a DEA agent cannot individually authorize that which the law does not sanction or permit. See *Off. of Personnel Mgt. v. Richmond*, 496 U.S. 414, 420 (1990) (“[T]he United States is neither bound nor estopped by acts of its officers or agents in entering into an arrangement or agreement to do so cause to be done what the law does not sanction or permit.”) (citation omitted).<sup>5</sup>

Defendants may try to argue that this evidence is relevant to an equitable estoppel defense to their CSA violations. Not so. In the Sixth Circuit, the elements of equitable estoppel are: “(1) misrepresentation by the party against whom estoppel is asserted; (2) reasonable reliance on the misrepresentation by the party asserting estoppel; and (3) detriment to the party asserting estoppel.” *Premo v. U.S.*, 599 F.3d 540, 547 (6th Cir. 2010) (quoting *Michigan Exp., Inc. v. U.S.*, 374 F.3d 424, 427 (6th Cir. 2004)). As a preliminary matter, even if individual DEA agents made misrepresentations to certain Defendants, neither the DEA nor the federal government is the party against whom estoppel would be asserted in this case. Thus, no statements of individual DEA officials can be used as the basis for an estoppel argument against the claims of Cuyahoga and

---

<sup>4</sup> Additionally, in December 2007, DEA informed all registrants that any “[p]ast communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.” Dkt. #1944-6 at p. 1.

<sup>5</sup> See also *Wilber Nat. Bank of Oneonta, N.Y., v. U.S.*, 294 U.S. 120, 123-24 (1935) (same; “Also, those dealing with an agent of the United States must be held to have had notice of the limitation of his authority.”); *Niewiadomski v. U.S.*, 159 F.2d 683, 688 (6th Cir. 1947) (same; “Government officers may not waive the provisions of the National Service Life Insurance Act.”); *U.S. v. City of Menominee, Mich.*, 727 F. Supp. 1110, 1121 (W.D. Mich. 1989) (“[R]egardless of any ‘admissions’ made by USEPA officials, ‘generally speaking public officers have no power or authority to waive the enforcement of the law on behalf of the public.’”) (citation omitted); *Washington Tour Guides Ass’n v. Natl. Park Serv.*, 808 F. Supp. 877, 881-82 (D.D.C. 1992) (“The National Park Service is not bound by oral agreements made by its officers when those agreements contravene clear regulatory language.”); *U.S. v. Articles of Drug . . . Hormonin*, 498 F. Supp. 424, 435-36 (D.N.J. 1980) (noting that this “general rule has been applied several times in the context of statements and representations made by agents of the FDA”), *aff’d sub nom. App. of Carnrick Laboratories, Inc.*, 672 F.2d 902 (3d Cir. 1981), and *aff’d sub nom. U.S. v. Articles of Drug*, 672 F.2d 904 (3d Cir. 1981).

Summit Counties. *See Niewiadomski*, 159 F.2d at 688 (“In order create estoppel it is necessary that misrepresentation be made by the party sought to be estopped.”).

Regardless, it is well established that the government “ ‘may not be estopped on the same terms as any other litigant.’ ” *Premo*, 599 F.3d at 547 (quoting *Heckler v. Community Health Services of Cranford County, Inc.*, 467 U.S. 51, 60 (1984)).<sup>6</sup> “When the Government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined.” *Heckler*, 467 U.S. at 60. Estoppel may not be invoked “as a means of successfully avoiding the requirements of legislation enacted for the protection of the public interest.” *P. Shrimp Co. v. U.S., Dept. of Transp.*, 375 F. Supp. 1036, 1042 (W.D. Wash. 1974) (“An administrative agency charged with protecting the public interest, is not precluded from taking appropriate action nor can the principles of equitable estoppel be applied to deprive the public of a statute’s protection because of mistaken action or lack of action on the part of public officials.”).<sup>7</sup>

Thus, a “ ‘party attempting to estop the government bears a very heavy burden’ in sustaining its argument.” *Michigan Exp.*, 374 F.3d at 427 (citation omitted); *see also Premo*, 599 F.3d at 547.<sup>8</sup> That party, “[a]t a minimum . . . must demonstrate some ‘affirmative misconduct’ by the government in addition to the other estoppel elements.” *Michigan Exp.*, 374 F.3d at 427 (citation

---

<sup>6</sup> *See also Off. of Personnel Mgt.*, 496 U.S. at 419 (“From our earliest cases, we have recognized that equitable estoppel will not lie against the Government as it lies against private litigants.”); *Michigan Exp.*, 374 F.3d at 427.

<sup>7</sup> *See also U.S. v. 789 Cases, More or Less, of Latex Surgeons’ Gloves, an Article of Device*, 799 F. Supp. 1275, 1297 (D.P.R. 1992) (“It is . . . clear that one cannot invoke estoppel to avoid the requirements of legislation, such as the [Federal Food, Drug, and Cosmetic] Act, which was enacted to protect the public from products that do not comply with the law. . . . Claimant is, in effect, asking this Court to enjoin the FDA from enforcing the law. It is beyond dispute that the government may not be enjoined from enforcing the Act; such relief would merely permit illegal conduct to continue to the detriment of the public.”); *Hormonin*, 498 F. Supp. at 435 (“I have serious reservations as to whether equitable estoppel could ever be invoked to prevent enforcement of the policy of the [Federal Food, Drug, and Cosmetic] Act, i.e., the protection of the public health and safety.”).

<sup>8</sup> *See also Off. of Personnel Mgt.*, 496 U.S. at 422 (noting that it had reversed every finding of estoppel against the government that had come before it).

omitted); *see also Premo*, 599 F.3d at 547. “Affirmative misconduct” requires “ ‘more than mere negligence[;]’ ” the government must have “either intentionally or recklessly misle[d] the claimant.” ” *Premo*, 599 F.3d at 547 (quoting *Michigan Exp.*, 374 F.3d at 427);<sup>9</sup> *see also Fisher v. Peters*, 249 F.3d 433, 444–45 (6th Cir. 2001) (“[A] litigant claiming equitable estoppel against the Government must establish, in addition to the traditional elements, more than mere negligence, delay, inaction, or failure to follow an internal agency guideline.”) (citation and internal quotation marks omitted).<sup>10</sup> “The party asserting estoppel against the government bears the burden of proving an intentional act by an agent of the government and the agent’s requisite intent.” *Michigan Exp.*, 374 F.3d at 427. *See also Premo*, 599 F.3d at 547.

Additionally, even assuming, *arguendo*, that Defendants had evidence of affirmative misconduct by an individual DEA agent, they must still satisfy the other estoppel elements. *See Michigan Exp.*, 374 F.3d at 427 (citation omitted); *Premo*, 599 F.3d at 547. They cannot do so. The “party claiming the estoppel must have relied on its adversary’s conduct ‘in such a manner as to change his position for the worse[;]’ and that reliance must have been reasonable in that the party

---

<sup>9</sup> “As the Supreme Court has pointed out, punishing the good-faith and conscientious efforts of the government by an easy rule of estoppel ‘might create not more reliable advice, but less advice. . . .’ We wish to avoid that consequence.” *Michigan Exp.*, 374 F.3d at 428 (quoting *Off. of Personnel Mgt.*, 496 U.S. at 433).

<sup>10</sup> *See also Abercrombie & Fitch Stores, Inc. v. Am. Com. Const., Inc.*, 2:08-CV-925, 2010 WL 1640883, at \*3 (S.D. Ohio Apr. 22, 2010) (“Estoppel does not apply where ‘[t]he government was not attempting to trick’ the party asserting estoppel, but was rather ‘attempting, in good-faith, to advise [the party] as to its intended course of action based on the facts that it knew,’ and not acting with malicious intent.”) (quoting *Michigan Exp.*, 374 F.3d at 428); *Green v. U.S.*, 8 F. Supp. 2d 983, 994-95 (W.D. Mich. 1998) (“The Greens argue that the affirmative misconduct requirement is satisfied through the statements made by Rosenquist, Hare, and other Defendants that the Greens were first on the list to have their loan funded. At most, the statements were made based upon an erroneous application of FSA regulations, and constitute no more than mere negligence. Such statements do not rise to the level of affirmative misconduct required for an estoppel claim against the government.”) (internal citation omitted); *Highland Park Patient Collective, Inc. v. U.S. Dept of J.*, CV1209958RGKFFMX, 2013 WL 12142958, at \*4 (C.D. Cal. Mar. 20, 2013) (“Plaintiff fails to identify any ‘affirmative misconduct’ on the part of a government official, but merely points to government memoranda and unofficial statements that induced Plaintiff to believe that the CSA would not be enforced against it. These facts are insufficient to demonstrate affirmative misconduct. Accordingly, Plaintiff’s estoppel claim fails.”) (internal citation omitted).

claiming the estoppel did not know nor should it have known that its adversary's conduct was misleading." *Heckler*, 467 U.S. at 59 (internal footnote omitted).<sup>11</sup>

Defendants could not have reasonably relied on any statements by individual DEA agents that contradicted the requirements set forth by the CSA.<sup>12</sup> "[T]hose who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law." *Heckler*, 467 U.S. at 63.<sup>13</sup> Thus, as registrants, Defendants were obligated to familiarize themselves with the legal requirements of the CSA. *Cf. Heckler*, 467 U.S. at 64 ("As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement."). Moreover, as noted above (*supra* at pp. 12-13 & fn.4), Defendants knew that the DEA had expressly disclaimed the idea that it ever "approved" or "endorsed" any particular

---

<sup>11</sup> See also *id.* at 59 n.10 ("The truth concerning these material facts must be unknown to the other party claiming the benefit of the estoppel, not only at the time of the conduct which amounts to a representation or concealment, but also at the time when that conduct is acted upon by him. If, at the time when he acted, such party had knowledge of the truth, or had the means by which with reasonable diligence he could acquire the knowledge so that it would be negligence on his part to remain ignorant by not using those means, he cannot claim to have been misled by relying upon the representation or concealment.") (citation omitted); *Farmers Home Admin. v. Call*, 145 F.3d 1331, 1998 WL 246038, at \*2 (6th Cir. 1998); *Abercrombie*, 2010 WL 1640883, at \*3.

<sup>12</sup> This is particularly true with respect to any oral statements made by individual DEA agents. See *Heckler*, 467 U.S. at 65 ("The necessity for ensuring that governmental agents stay within the lawful scope of their authority, and that those who seek public funds act with scrupulous exactitude, argues strongly for the conclusion that an estoppel cannot be erected on the basis of the oral advice that underlay respondent's cost reports. That is especially true when a complex program such as Medicare is involved, in which the need for written records is manifest."); *Farmers*, 1998 WL 246038, at \*3 (same).

<sup>13</sup> See also *Wilber*, 294 U.S. at 124 ("The statutes and regulations which govern the War Risk Insurance Bureau we must assume are known by those who deal with it."); *D & S Remodelers, Inc. v. Wright Natl. Flood Ins. Services, LLC*, 725 Fed. Appx. 350, 357 (6th Cir. 2018) (unpublished) ("[T]hose who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.") (quoting *Heckler*, 467 U.S. at 63); *Farmers*, 1998 WL 246038, at \*3 ("Call cannot use the faulty advice of a governmental agent as the sole grounds for asserting estoppel against the government."); *ADR Tr. Corp. v. Cheshire Mgt. Co., Inc.*, 842 F. Supp. 295, 299 (W.D. Tenn. 1992) ("A private party cannot exert equitable estoppel to permit the statements of government agents to waive or revise the laws as enacted by Congress."); *City of Menominee*, 727 F. Supp. at 1122 ("MPC is a sophisticated corporate player, represented by experienced counsel, heavily involved in activities that are pervasively regulated by both Michigan and USEPA. It is disingenuous for MPC to now assert, in its words, that it simply 'assumed all was well' with the 1979 permit despite the signs that USEPA might insist on the continuing applicability of the 1973 permit.").

SOM programs. *Cf. Hormonin*, 498 F. Supp. at 436-37 (rejecting defendant's equitable estoppel defense because, *inter alia*, FDA's publication of a notice in the Federal Register, under which all opinions previously given by the FDA to the effect that an article was not "new drug" were revoked, plainly operated as a revocation of the FDA's opinion letter which stated that particular drug would not require clearance under "new drug" procedure with adequate labeling).

Defendants may also try to argue that this evidence is relevant to the issue of intent or knowledge under CSA §§ 841 or 843. Section 841(a) provides that "[e]xcept as authorized by [Subchapter I of the CSA], it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance." 21 U.S.C. § 841(a). Section 843 makes it unlawful for registrants to "knowingly or intentionally . . . furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II[.]" 21 U.S.C. § 843(a)(4). Plaintiffs anticipate that some Defendants will claim that they could not have "knowingly or intentionally" violated the CSA because individual DEA agents purportedly told them their SOM programs were compliant. This argument is without merit.

The United States Supreme Court has stated that "unless the text of the statute dictates a different result, the term 'knowingly' merely requires proof of knowledge of the facts that constitute the offense[;]" it is not necessary to prove that the defendant knew its conduct was unlawful. *Bryan v. U.S.*, 524 U.S. 184, 192-93 (1998) (internal footnote omitted).<sup>14</sup> Similarly, "to commit an act intentionally is to do so deliberately and not by accident." *Fuller*, 162 F.3d at 260. *See also* Dkt. #2545 at p. 77. Nothing in the text of § 841 or § 843 indicates that Congress meant to punish only

---

<sup>14</sup> *See also U.S. v. Fuller*, 162 F.3d 256, 260 (4th Cir. 1998) ("To act 'knowingly' is to act with 'knowledge of the facts that constitute the offence' but not necessarily with knowledge that the facts amount to *illegal* conduct, unless the statute indicates otherwise.") (quoting *Bryan*, 524 U.S. at 192-93) (emphasis in original); *U.S. v. Scarmazzzo*, 554 F. Supp. 2d 1102, 1107 (E.D. Cal. 2008) ("Where the crime requires only knowledge, not willfulness, [Plaintiffs] need only prove the Defendants knew they were performing an act, not that they knew the act was unlawful or criminalized by statute."), *aff'd sub nom. U.S. v. Montes*, 421 Fed. Appx. 670, 673 (9th Cir. 2011) (unpublished).

those defendants who actually intended to violate the statute or knew their conduct was illegal.<sup>15</sup> Ignorance of the law is not a defense to these general-intent crimes. *See Walsh*, 654 Fed. Appx. at 698 (“[T]he Supreme Court has identified only a few areas, such as tax law, where ignorance of the law is a defense, and that is because the tax system is so complex. *The CSA is not such a ‘highly technical statute’* [ ],” and presents little to no ‘danger of ensnaring individuals engaged in apparently innocent conduct.’ ”) (internal citation omitted) (emphasis added).<sup>16</sup> Accordingly, evidence of a Defendant’s good-faith belief that its conduct is lawful is irrelevant and properly excluded at trial. *See Barnes*, 677 Fed. Appx. at 278 (“Under the Federal Rules of Evidence, a party is not entitled to present evidence at trial that is not relevant. Relevancy determinations are within the district court’s discretion, and evidence that neither negates an element of the crime charged nor establishes a defense is not relevant. Because the manufacture of marijuana is a general-intent crime, and ignorance of the law is

---

<sup>15</sup> *See, e.g., U.S. v. Barnes*, 677 Fed. Appx. 271, 277-78 (6th Cir. 2017) (unpublished) (defendant charged with manufacturing marijuana in violation of § 841(a); “General-intent crimes require that a defendant ‘knowingly’ committed the criminal act. . . . [The defendant] *knew* he was growing marijuana—and that knowledge is the only knowledge required to convict him under the statute.”); *Walsh*, 654 Fed. Appx. at 698 (unpublished) (“The Government was not required to show that Jenkins knew of, or intended to violate, federal drug laws.”); *U.S. v. Tobin*, 676 F.3d 1264, 1279–80 (11th Cir. 2012) (“The District Court’s conclusion that the mens rea under Section 841(a)(1) is knowledge rather than willfulness is correct. . . . The language of the statute does not refer, in any way, to willfulness, and as a consequence, we have said that the government only needs to prove that the defendant acted knowingly.”); *U.S. v. Ansaldi*, 372 F.3d 118, 128 (2d Cir. 2004) (“It is unlawful for an individual ‘knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.’ 21 U.S.C. § 841(a)(1). Knowledge of, or intent to violate, the law is simply not an element of this offense.”); *Fuller*, 162 F.3d at 260 (“[I]t is not a requirement of 21 U.S.C. § 841(a) that the defendant have specifically intended to violate the statute in order to be found guilty.”); “[N]othing in the text of 21 U.S.C. § 841(a) indicates that Congress meant to punish only those defendants who actually intended to violate the statute[.]”); *Scarmazzo*, 554 F. Supp. 2d at 1109 (“It is not an element of § 841 that Defendant intended to violate a statute.”); *U.S. v. Hoyt*, 2:14CR00001, 2014 WL 5023093, at \*7 (W.D. Va. Oct. 8, 2014).

<sup>16</sup> *See also McFadden v. U.S.*, 135 S. Ct. 2298, 2304 (2015) (noting that “ignorance of the law is typically no defense to criminal prosecution” and “a defendant who knows he is distributing heroin but does not know heroin is listed on the schedules” would “be guilty of knowingly distributing ‘a controlled substance’ ” under § 841(a)); *Barnes*, 677 Fed. Appx. at 277-78 (“This intent requirement goes to whether the defendant knew he was engaging in the act, not whether the defendant knew that his actions were illegal. Ignorance of the law is no defense to a general-intent crime. The defendant’s good-faith belief in the legality of his conduct cannot negate an element of the charges.”); *Tobin*, 676 F.3d at 1280 n.6; *Hoyt*, 2014 WL 5023093, at \*7.



not a defense, evidence that Barnes believed he could manufacture large quantities of marijuana in his home for the ONAC, pursuant to a RFRA exemption, is irrelevant.”) (internal citations omitted).<sup>17</sup>

Accordingly, the statements of individual DEA agents purporting to “approve” or “endorse” a particular Defendant’s SOM program are not relevant to any issue in this case. They are not probative of the scope of Defendants’ duties under the CSA; that issue has already been determined by the Court as a matter of law. They also are not probative of whether or not a particular Defendant violated its duties under the CSA, or whether such violations were knowing or intentional. Moreover, admitting this evidence would unfairly prejudice Plaintiffs, confuse the issues, mislead the jury, waste time, and cause undue delay. The jury is likely to mistakenly conflate these statements of individual DEA agents with official proclamations from the DEA and give undue weight to those statements as a result. *Cf. Walker ex rel. his Ct. Appointed Curator v. United Healthcare of Hardin, Inc.*, 3:07-00067-JHM, 2010 WL 3092648, at \*6-7 (W.D. Ky. Aug. 6, 2010) (granting plaintiff’s motion *in limine* to preclude evidence of investigation report prepared by representative from the Office of Inspector General that concluded that the investigation failed to substantiate abuse or neglect; “[A] jury could potentially attach undue weight to this type of agency determination by viewing it improperly as a finding by the OIG that Lincoln Trail did not violate its standard of care in its treatment of Plaintiff.”); *Wright v. Columbia Sussex Corp.*, 3:06-CV-190, 2008 WL 972699, at \*1 (E.D. Tenn. Apr. 7, 2008) (granting plaintiff’s motion *in limine* to preclude

---

<sup>17</sup> See also *Tobin*, 676 F.3d at 1280 (“[F]or the distribution counts, the District Court correctly granted the government’s motion in limine to exclude evidence that the defendant subjectively believed that they were not committing the offenses. As the District Court explained, because the mens rea under Section 841(a)(1) consists of knowledge rather than willfulness, any evidence that the defendants had a sincere belief that their distribution of controlled substances was in conformity with the law would be ‘irrelevant’ to the distribution counts and thus inadmissible in that respect.”); *Hoyt*, 2014 WL 5023093, at \*6-7 (granting government’s motion “to preclude the defendants from arguing or introducing any evidence showing that they did not know . . . that it was illegal to distribute [controlled substance analogues]”; “[T]here is no statutory requirement in the CSAEA that the defendants realize that their actions were illegal. Therefore, any arguments or evidence presented by the defendants that they did not know that these substances were illegal would be tantamount to an ignorance-of-the-law defense, which is not a valid defense to the charges the defendants face.”).

evidence of EEOC Dismissal and Notice of Rights letter; “A jury could attach undue weight to the ‘No Cause Finding’ and view it as a suggestion there was no retaliation, as opposed to merely finding that the agency found no probable cause.”); *Cuadra v. Univision Commun., Inc.*, CV 09-4946(JLL), 2013 WL 12153536, at \*1 (D.N.J. Jan. 14, 2013) (granting plaintiff’s motion to exclude EEOC’s “no probable cause” determination; “[A]dmitting the EEOC determination here will cause jury confusion and undue delay because it will require a mini-trial to provide adequate time for its foundation, context, and rebuttal, but the EEOC’s findings are not binding on the jury in any event. In addition, Plaintiff is likely to be unfairly prejudiced because the jury is likely to give undue weight to the determination due to the fact that it was issued by a governmental body which specializes in that area.”).

16. **Any suggestion or argument that the DEA’s failure to sanction or initiate enforcement actions against a particular Defendant demonstrates a determination by the DEA that the Defendant complied with the CSA or its implementing regulations, or gives rise to a presumption that Defendants complied with same.**

*See* below at MIL No. 17. For efficiency’s sake, Plaintiffs have combined their argument on MIL Nos. 16 and 17.

17. **Any suggestion or argument that the FDA’s failure to sanction or initiate enforcement actions against a particular Defendant demonstrates a determination by the FDA that the Defendant complied with the Federal Food, Drug, and Cosmetic Act or FDA regulations, or gives rise to a presumption that Defendants complied with same.**

For the same reasons discussed above with respect to MIL No. 15, the Court should preclude Defendants from suggesting or arguing that: (i) the DEA’s failure to sanction, or initiate enforcement actions against, a particular Defendant demonstrates a determination by the DEA that the Defendant complied with the CSA or its implementing regulations, or gives rise to a presumption that Defendants complied with same; or (ii) the FDA’s failure to sanction, or initiate enforcement actions against, a particular Defendant demonstrates a determination by the FDA that the Defendant complied with the Federal Food, Drug, and Cosmetic Act or FDA regulations, or gives rise to a presumption that Defendants complied with same. The fact that a Defendant has not



been sanctioned or the subject of an enforcement action does not mean that Defendant did not violate the CSA, the FDCA, and/or related regulations. *See Georges*, 2013 WL 5217198, at \*6 (granting plaintiff's motion *in limine* "to exclude any comments or argument that the absence of any evidence of FDA sanction is proof of full and timely compliance with FDA regulations[.]" stating: "[T]he fact that Defendant has not been cited by the FDA for its labeling, marketing, or subject drugs is not proof of compliance with FDA regulations. This evidence is also excluded under [Rule] 403 as likely to cause delay and to mislead and confuse the jury."); *Hoyt*, 2014 WL 5023093, at \*6-7 (granting government's "motion to exclude any evidence relating to the government's failure to notify the defendants that they were violating the CSAEA, including cease-and-desist letters sent to other retailers in this district for selling the same substances[.]" noting "it could only be offered to show the defendants' lack of knowledge of illegality[.]" "which is not a valid defense to the charges the defendants face").

Moreover, a defendant may not invoke an equitable estoppel defense based on government inaction. *See Fisher*, 249 F.3d at 444–45 ("[A] litigant claiming equitable estoppel against the Government must establish, in addition to the traditional elements, more than mere negligence, delay, inaction, or failure to follow an internal agency guideline.") (citation and internal quotation marks omitted); *U.S. v. City of Toledo*, 867 F. Supp. 603, 607 (N.D. Ohio 1994) ("Although the doctrine of equitable estoppel may be used in circumstances of deliberate and egregious misconduct where a governmental agency has acted affirmatively, it is not available where the agency has simply acted in an indifferent, passive, or negligent manner. The record in this case shows, at worst, inaction on the part of the EPA and State EPA, despite awareness of the circumstances and the risks that they posed for the City and similarly situated permit holders. That inaction was not, however, purposefully undertaken to cause harm or injury to the City. It reflects, rather, the difficulties encountered by the agencies as they sought to resolve complex regulatory and policy issues."<sup>18</sup> Indeed, in similar circumstances, the D.C. Circuit Court of Appeals rejected a

---

<sup>18</sup> *See also City of Menominee*, 727 F. Supp. at 1121–22 ("Mere inaction by USEPA in the face of known (footnote continues on next page)

defendant's argument that the DEA's failure to identify deficiencies in the defendant's SOM program following a compliance review estopped the government from holding the defendant to account for inadequacies in its diversion-detection policies and practices. *Masters Pharm., Inc. v. Drug Enf't Administration*, 861 F.3d 206, 223-25 (D.C. Cir. 2017). The court stated:

[E]ven if the DEA review addressed the SOMS in operation, and even if [the defendant] had reason to and did rely on that review, there is no evidence suggesting that the government engaged in the "affirmative misconduct" necessary to sustain a claim of estoppel against the government. The bar for establishing "affirmative misconduct" is high, requiring a showing of "misrepresentation or concealment, or, at least, behav[ior] . . . that . . . will cause an egregiously unfair result."

*Id.* at 225 (internal citation omitted).

18. **Any reference that any award of damages will adversely affect the ability of any member of the jury to purchase, or have available medications in the future, or affect the cost thereof, or have an adverse effect on the drugs or health products available to individuals or industries in the United States or elsewhere (e.g., argument or testimony that if Plaintiffs are awarded damages, the cost of medicines or medical care will increase, or that medications will no longer be available.).**

Evidence or argument suggesting that the outcome of these cases will affect the ability of the jurors to purchase or have available medications in the future is similar to "golden rule" arguments, which are universally prohibited. Such arguments encourage the members of the jury to decide the case based on improper factors rather than the evidence presented in the case. Evidence or

---

NPDES permit violations is not affirmative misconduct upon which equitable estoppel will lie."); 789 *Cases*, 799 F. Supp. at 1296–97 ("Claimant does not obtain a waiver to distribute illegal products because the government has not enforced the law against it previously. In fact, should the government find that FDA or its agents failed to enforce the law previously, for whatever reason, the agency has a duty to correct this earlier position. . . . To stop the government from enforcing the GMP regulations because it failed to do so earlier would deprive the public of the protection that the law is designed to establish.") (internal citation omitted); *Moran Mar. Associates v. U.S. Coast Guard*, 526 F. Supp. 335, 342 (D.D.C. 1981) ("The Court agrees that prior inaction by the Coast Guard does not now bar the agency from implementing the clear mandate of the regulation and its authorizing statute."), *aff'd sub nom. Moran Mar. Associates Am. Waterways Operators, Inc. v. U.S. Coast Guard*, 679 F.2d 261 (D.C. Cir. 1982); *Washington Tour Guides*, 808 F. Supp. at 882 ("[T]he government may not be estopped from enforcing the law, even following an extended period of no enforcement or underenforcement. . . . The Plaintiffs may well have been allowed by the National Park Service to operate their business on national park grounds for many years, but given the substantial, and undisputed, public interest in preserving national parks, the government cannot be estopped from fulfilling its duty to protect the public interest in accordance with specific regulations despite prior failure to enforce those regulations.").

argument of this nature is improper and inadmissible because (1) it is not relevant to any issue to be decided in these cases (Rules 401, 402); and (2) the probative value of such evidence is substantially outweighed by the risk of unfair prejudice, confusing the issues, and misleading the jury (Rule 403). *See Levaquin*, 2011 WL 6888533, at \*1 (granting plaintiff's motions *in limine* to exclude "evidence that tends to suggest in any way that an award of damages in this case will adversely affect the public's access to medications[,] "evidence that this or any other case in the MDL may cause an increase in the cost of purchasing or maintaining insurance[,] or "evidence that this case or any other case in the MDL may cause an increase in the cost of medications"); *Yasmin*, 2011 WL 6740391, at \*16 (granting similar motion *in limine*);<sup>19</sup> *Vioxx*, 2005 WL 3164251, at \*1 (granting plaintiff's motion *in limine* to exclude "[a]ny reference that a verdict for the [p]laintiff will adversely affect the ability of any member of the jury to purchase or have available medications in the future, the cost of medicine, or the viability of the pharmaceutical industry[,] "[a]ny reference that this case or any Vioxx case may cause an increase in the cost of purchasing or maintaining on the market[,] and "[a]ny reference that this case or any other Vioxx case may cause an increase in the cost of purchasing medication for the public").

**19. Any suggestion or indication that a judgment in this case will have an adverse effect on the finances or ability of Defendants to compete in the marketplace, or that it may negatively affect the economy or lead to layoffs (*e.g., any argument or testimony that a judgment in this or any other case might force the company to lay off employees, or cut back on its business, or affect the local or other economy*).**

The issues to be decided in this case focus on the harms suffered by Plaintiffs as a result of Defendants' wrongful manufacture, distribution, sale, and marketing of their opioid products. The jury will be instructed to base its findings on the evidence in the case, including evidence of the amount of damages that should be awarded, if any. Arguments or evidence suggesting that the jury

---

<sup>19</sup> In *Yasmin*, the court also granted the plaintiff's motion *in limine* to exclude "[a]ny comment, evidence, testimony, inference or document mentioning that a verdict for the Plaintiff will or could take a prescription choice away from doctors[.]" noting such evidence or argument "is too speculative and irrelevant to the jury's consideration in this case." *Id.*

should not award damages, or should limit or reduce the amount of damages, based on anything other than the admissible evidence in this case would be improper.

While evidence of net worth or financial status of Defendants is admissible with respect to the issue of punitive damages, Defendants' ability to pay an award of damages, or the effect of an award of damages on their financial status or decision-making with regard to such things as layoffs, is not relevant to the issues to be decided in this case. Such evidence or arguments would encourage the jury to decide the case based on bias or prejudice rather than the evidence admitted at trial, which is improper. Accordingly, evidence or argument of this nature should be excluded under Rules 401, 402, and 403. *See Sadler*, 2013 WL 1385386, at \*3 ("evidence regarding the effect of this or other lawsuits on . . . the ability of device manufacturers to develop new products, the profitability of medical device companies, or the impact of this litigation on [the defendant's] employees" is inadmissible).<sup>20</sup>

**20. Any reference that a verdict for Plaintiffs will adversely impact pharmaceutical manufacturers' incentive or ability to develop new drugs.**

As discussed in the motion *in limine* points above, the jury will be asked to decide this case based on the evidence presented at trial regarding Defendants' opioid products, Defendants' conduct with respect to manufacturing, distributing, selling, and marketing those products, and

---

<sup>20</sup> *See also Tylenol*, 2016 WL 3125428, at \*5 (granting plaintiff's motion *in limine* to exclude argument or evidence that a verdict for the plaintiff will or could result in people losing their jobs or lead to lay-offs; "This evidence is irrelevant to the issues of this case and would be unduly prejudicial."), at \*6 (granting plaintiff's motion *in limine* to exclude any indication that defendants may have to pay a judgment entered in this case, that defendant have limited policy limits or cash, or the effect or results of such judgment upon the insurance rates, premiums, finances, or ability of defendants to compete in the marketplace), at \*8 (granting plaintiff's motion *in limine* to exclude any comment, evidence, testimony, inference, or documents mentioning, suggesting, or inferring that if defendants are made to pay a judgment, it may negatively affect the New Jersey economy or the economy of any state); *Yasmin*, 2011 WL 6740391, at \*16 (granting plaintiff's motion to exclude "a]ny comment, evidence, testimony, inference or document mentioning, suggesting or inferring that if Defendants are made to pay a judgment that it may negatively affect the Illinois economy or the economy of any state"); *Lavaquin*, 2011 WL 6888533, at \*1 (granting plaintiff's motion *in limine* to exclude "evidence that this or any other case in the multidistrict litigation ("MDL") may have a negative impact on Defendants' stock values"); *Vioxx*, 2005 WL 3164251, at \*1 (granting plaintiff's motion *in limine* to exclude "[a]ny reference that this case or any Vioxx case may have a negative impact on Merck's stock price or any other publicly traded pharmaceutical manufacturer").

Plaintiffs' injuries. Evidence or argument suggesting that the outcome of these cases may cause pharmaceutical manufacturers to no longer develop new drugs is also similar to "golden rule" arguments, which are universally prohibited. Such arguments encourage the members of the jury to decide the case based on improper factors rather than the evidence presented at trial. Evidence or argument of this nature is improper and inadmissible because (1) it is not relevant to any issue to be decided in these cases (Rules 401, 402); and (2) the probative value of such evidence is substantially outweighed by the risk of unfair prejudice, confusing the issues, and misleading the jury (Rule 403). *See Levaquin*, 2011 WL 6888533, at \*1 (granting plaintiff's motion *in limine* to exclude evidence that a verdict for plaintiff "will adversely impact pharmaceutical companies' incentive or ability to develop new medications"); *Vioxx*, 2005 WL 3164251, at \*1 (granting plaintiff's motion *in limine* to exclude "[a]ny reference that a verdict for the [p]laintiff will adversely impact pharmaceutical companies' incentive/ability to develop new medicines").

**21. Any reference to or suggestion that Defendants and the pharmaceutical industry have to factor in the overall cost of lawsuits when determining the cost of their products to the public (e.g., argument or testimony that lawsuits and claims force companies to charge more for their products).**

Defendants should also be precluded from offering evidence or argument that lawsuits impact the cost of their products for the same reasons discussed above regarding device regulation and "golden rule" arguments. *Supra* at MIL Nos. 18-20. Any such evidence or argument encourages the jury to decide the case based on impermissible factors rather than the evidence presented at trial and should be precluded because (1) it is not relevant to any issue to be decided in these cases (Rules 401, 402); and (2) the probative value of such evidence is substantially outweighed by the risk of unfair prejudice, confusing the issues, and misleading the jury (Rule 403).

**22. Any reference to deposition or trial testimony derived from witnesses produced only in litigation in which Plaintiffs did not participate, other than testimony that has been produced to Plaintiffs during discovery in this MDL that may be offered for impeachment purposes.**

Any evidence of or reference to former deposition or trial testimony from witnesses taken in parallel litigation in which Plaintiffs did not participate, other than testimony that has been produced

to Plaintiffs during discovery in this MDL that may be offered for impeachment purposes, should be excluded under Federal Rules of Civil Procedure 32(a)(1)(A) and 32(a)(8), and Federal Rule of Evidence 804(b)(1). Under these rules, because Plaintiffs (or their predecessors in interest) were not present to cross examine the witnesses, develop testimony and ensure its trustworthiness, the evidence should be excluded. Rule 32(a)(1)(A) provides that “[a]t a hearing or trial, all or part of a deposition may be used against a party” if several conditions are met, including that “the party was present or represented at the taking of the deposition or had reasonable notice of it[.]” FED. R. CIV. P. 32(a)(1)(A).<sup>21</sup> Similarly, Rule 32(a)(8) only allows a deposition taken in another proceeding to be “used in a later action *involving the same subject matter between the same parties* or their representatives or successors in interest.” FED. R. CIV. P. 32(a)(8) (emphasis added). Federal Rule of Evidence 804(b)(1) allows former testimony from a witness at a trial or deposition in a different proceeding only when both the witness is unavailable and a party or its predecessor in interest had “an opportunity and similar motive to” examine the witness.<sup>22</sup>

“The Federal Rules of Civil Procedure and Evidence set forth the limited circumstances under which prior deposition testimony may be used in a subsequent proceeding.” *Guthrie v. Ball*, No. 1:11-CV-333-SKL, 2014 WL 11581410, at \*16 (E.D. Tenn. Oct. 10, 2014) (granting motion *in limine* to exclude reference to any deposition testimony taken outside the litigation under FRCP 32(a)(8) and FRE 804(b)(1)). As noted by the Sixth Circuit:

Rule 804(b)(1) requires that the party against whom the evidence is offered or a predecessor in interest must have an opportunity to develop the testimony by direct, cross, or redirect examination. The opportunity to examine the declarant provides

---

<sup>21</sup> Rule 32(a)(1) further only allows a deposition to be used “to the extent it would be admissible under the Federal Rules of Evidence if the deponent were present and testifying; and the use is allowed by Rule 32(a)(2) through (8).” FED. R. CIV. P. 32(a)(1)(B) & (C).

<sup>22</sup> Rule 804(b) provides in full: “The following are not excluded by the rule against hearsay if the declarant is unavailable as a witness: (1) Former Testimony. Testimony that: (A) was given as a witness at a trial, hearing, or lawful deposition, whether given during the current proceeding or a different one; and (B) is now offered against a party who had—or, in a civil case, whose predecessor in interest had—an opportunity and similar motive to develop it by direct, cross-, or redirect examination.” FED. R. EVID. 804(b).

safeguards similar to the circumstantial guarantees of trustworthiness found in other exceptions to the hearsay rule. Because the opportunity to develop the former testimony is necessary to ensure the trustworthiness of that testimony, the prior testimony should not be admitted unless such an opportunity was afforded.

*Complaint of Paducah Towing Co., Inc.*, 692 F.2d 412, 418-19 (6th Cir. 1982) (internal citations omitted) (reversing district court for admitting the testimony into evidence); *see also Murphy v. Owens-Illinois, Inc.*, 779 F.2d 340, 343–44 (6th Cir. 1985) (deposition from prior case in which defendant was not a party was inadmissible); *In re Polyurethane Foam Antitrust Litig. Direct Purchaser Class*, 1:10 MD 2196, 2015 WL 12747961, at \*14 (N.D. Ohio Mar. 6, 2015) (denying defendant’s request to use deposition testimony taken in a companion *Urethane Antitrust Litigation* case at trial; “Because Plaintiffs had no predecessor or other representative at the *Urethane* depositions of these witnesses, the testimony is not admissible.”).

Moreover, the Special Master specifically limited production of such transcripts in Discovery Ruling No. 9 to depositions taken “on or before January 25, 2019.” Dkt. #1118 at 2, 4. Although the recently-entered Discovery Ruling No. 22 has now expanded that ruling to require Defendants to produce deposition transcripts from other proceedings on an ongoing basis, the fact remains that Plaintiffs did not have the benefit of post-January 25 transcripts during the discovery period and were therefore deprived of the opportunity to take meaningful discovery of their contents.

**23. Any argument or suggestion that the “learned intermediary” doctrine limits the liability of any Defendant or absolves any Defendant from liability.**

The “learned intermediary” doctrine is recognized in Ohio as a common law doctrine, and it has been codified as well. The Ohio Supreme Court described the doctrine in *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 834 (Ohio 1981), as follows:

A manufacturer of an unavoidably unsafe ethical (prescription) drug is not strictly liable in tort to a consumer who has suffered injury as a result of ingesting that drug where the manufacturer has provided adequate warning to the medical profession of all potential adverse reactions inherent in the use of the drug of which the manufacturer, being held to the standards of an expert in the field, knew or should have known to exist at the time of marketing.



The doctrine is also codified at Ohio Rev. Code Ann. § 2307.76(C), which states in relevant part as follows:

An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

The learned intermediary doctrine modifies the normal rule that a manufacturer of a product is required to provide adequate warnings to the end user. With prescription drugs, a manufacturer is ordinarily required to provide warnings only to physicians, who assess the risks and benefits of their patient using the drug.

Defendants should be precluded from offering argument or evidence that they are absolved from liability, or that their liability should be limited in any way, or that they fulfilled their obligations under the “learned intermediary” doctrine. The focus of the “learned intermediary” doctrine is on *who* the drug manufacturer is required to warn; it permits the manufacturer to warn the prescribing doctor rather than the end-user of the product. Plaintiffs do not contend that their injuries were caused by Defendants’ failure to provide an adequate warning to them or to any patient. Rather, they contend that Defendants marketed their prescription opioids through false and misleading statements which both overstated the benefits of those drugs and understated the risks associated with their use. Thus, the issue is not *who* received the warning, but rather what the Defendants said and to what extent their statements were false and misleading. For this reason, the ability of a drug manufacturer to meet its warnings burden by warning the doctor instead of the patient is irrelevant. Plaintiffs further note that, to the extent Defendants use the term “learned intermediary” to refer to their theory that the actions of doctors break the causal chain between Defendants’ fraud and Plaintiffs’ injuries, that argument has nothing to do with the “learned intermediary” defense and can only serve to confuse the jury by dressing in apparent legal garb an argument that has nothing to do with the doctrine being invoked.



**24. Any reference to, or evidence of, any alleged “failure to mitigate” by Plaintiffs.**

Defendants should be precluded from offering any evidence or argument that either Cuyahoga County or Summit County “failed to mitigate” any damages they are claiming in this case. As a general rule, Ohio law utilizes a traditional “mitigation of damages” (sometimes referred to as the “doctrine of avoidable consequences”) doctrine which provides that “[o]ne injured by the tort of another is not entitled to recover damages for any harm that he could have avoided by the use of reasonable effort or expenditure after the commission of the tort.” *BP Exploration & Oil Co. v. Maint. Servs., Inc.*, 313 F.3d 936, 943–44 (6th Cir. 2002) (citing *Johnson v. Univ. Hosps. of Cleveland*, 540 N.E.2d 1370, 1377 (Ohio 1989)). However, there are several reasons why that doctrine should not be applied in this case.

First, “the obligation to mitigate does not require the party to incur extraordinary expense and risk.” *Chicago Title Ins. Co. v. Huntington Natl. Bank*, 1999-Ohio-62, 719 N.E.2d 955, 961-2 (Ohio 1999) (citing *S & D Mechanical Contrs., Inc. v. Enting Water Conditioning Sys., Inc.* 593 N.E.2d 354 (Ohio App. 2 Dist. 1991)). And, “[t]he rule requiring one injured by a wrongful act of another to minimize the resulting damages does not require a party to do what is unreasonable or impracticable.” *Parrish v. Machlan*, 722 N.E.2d 529, 532 (Ohio App. 1 Dist. 1997) (citing *Four Seasons Envtl., Inc. v. Westfield Cos.*, 638 N.E.2d 91, 92 (Ohio App. 1st Dist. 1994); *Foust v. Valleybrook Realty Co.*, 446 N.E.2d 1122, 1127 (Ohio App. 6th Dist. 1981)). It is undisputed that both counties incurred significant costs and expense, and required the use of extensive government resources, in their efforts to address the opioid crises in their respective communities. Government expenses always represent a balance between available revenue and public need, and governments do not have the same flexibility to reallocate expenditures and resources as individuals and corporations do. Thus, in light of the fact that these governments *did* incur extraordinary expenses, which necessarily deprived them of the ability to use those expenditures on other needs, Defendants should be precluded from arguing they should have done even more.

Second, “[w]hen both parties have the same opportunity to reduce damages, a defendant cannot later contend that the plaintiff failed to mitigate.” *Chicago Title*, 719 N.E.2d at 962. Plaintiffs

have alleged that the harms caused in their communities resulted from Defendants' false and misleading marketing of their prescription opioid medications and their failure to adequately monitor and control the distribution of those dangerous products. Defendants should be precluded from arguing the counties should have done more when it was the Defendants' conduct that caused the problem in the first place. This is particularly compelling because if the Defendants had not falsely marketed their products, or had ceased doing so when the opioid crisis became apparent, and had used adequate distribution controls from the beginning, or implemented them sooner, those actions may have helped reduce the severity of harm suffered by the Plaintiffs.

Third, the general rule of mitigation of damages/avoidable consequences is discussed in the RESTATEMENT (SECOND) OF TORTS § 918. That section states as follows:

- (1) Except as stated in Subsection (2), one injured by the tort of another is not entitled to recover damages for any harm that he could have avoided by the use of reasonable effort or expenditure after the commission of the tort.
- (2) One is not prevented from recovering damages for a particular harm resulting from a tort if the tortfeasor intended the harm or was aware of it and was recklessly disregardful of it, unless the injured person with knowledge of the danger of the harm intentionally or heedlessly failed to protect his own interests.

Subsection 1 describes the general mitigation rule followed in Ohio, and has been cited favorably by the Ohio Supreme Court. *See Johnson*, 540 N.E.2d at 1377. Although Subsection 2 has not been specifically cited by any Ohio case (state or federal) Plaintiffs were able to locate, the rule makes sense. Where a defendant acts intentionally or recklessly, it should not be afforded the same courtesies as one who merely acts negligently. Applying that rule to this case, Defendants should be precluded from arguing Cuyahoga County and Summit County failed to mitigate their damages when the harms were caused by Defendants' intentional conduct in fraudulently misrepresenting their prescription opioid medications and in failing to impose adequate measures to oversee and control the distribution of those drugs.

Finally, numerous courts have held that the federal government has no duty to mitigate damages in fraud actions, including those brought under the False Claims Act. *See, e.g., United States v. United Techs. Corp.*, 950 F. Supp.2d 949, 954 (S.D. Ohio 2013); *U.S. v. Associates in Eye Care, P.S.C.*,

13-CV-27-GFVT, 2014 WL 12606508, at \*5 (E.D. Ky. Nov. 14, 2014); *U.S. ex rel. Garrison v. Crown Roofing Services, Inc.*, CIV.A. H-07-1018, 2011 WL 4914971, at \*2 (S.D. Tex. Oct. 14, 2011); *U.S. ex rel. Monahan v. Robert Wood Johnson U. Hosp. at Hamilton*, CIV. A. 02-5702 JAG, 2009 WL 4576097, at \*8 (D.N.J. Dec. 1, 2009); *U.S. v. Aging Care Home Health, Inc.*, CIVA 3-02-2199, 2006 WL 2915674, at \*1 (W.D. La. Oct. 6, 2006). The same rule should apply in this case. In a False Claims Act case, the federal government (directly or through a relator) is enforcing the public right to eliminate fraudulent claims which deplete federal treasuries, and here, Plaintiffs are seeking similar relief: seeking damages and other relief caused by strains on their resources directly caused by the Defendants. Defendants should not be permitted to second guess or critique Plaintiffs efforts to address a crisis caused by Defendants themselves.

#### **PLAINTIFF-SPECIFIC LIMINE REQUESTS**

- 25. Any reference to, or evidence of, the identities of any children, including but not limited to children in child protective custody.**

*See* below at MIL No. 26. For efficiency's sake, Plaintiffs have combined their argument on MIL Nos. 25 and 26.

- 26. Any reference to, or evidence of, any individually identifiable health information or medical records related to any individual patients, including but not limited to information or records that identifies babies with neonatal abstinence syndrome or persons with opioid use disorder.**

Defendants should be precluded from disclosing facts that would potentially reveal the identity of any child, and in particular any child in protective custody;<sup>23</sup> or from disclosing individually identifiable health information related to any individual patients.<sup>24</sup> Plaintiffs anticipate

---

<sup>23</sup> Given the level of publicity this case has attracted, Plaintiffs do not believe that identifying information about any child (whether or not in protective custody) should be disclosed during trial. Such evidence is completely irrelevant and would be unfairly prejudicial to the child or children identified. Plaintiffs cannot imagine that Defendants would seek to admit such evidence, or make such a reference, but in an abundance of caution, Plaintiffs request that they be precluded from doing so without first receiving a ruling from the Court outside the presence of the jury.

<sup>24</sup> This type of protection was agreed to by the parties during the discovery phase of this litigation. (footnote continues on next page)

offering evidence regarding the nature of treatment and other services they have had to provide to their respective communities, as well as evidence about the future need for such services in order to address the opioid crisis, but do not intend to include any individualized or identifying information regarding specific children or patients. However, Defendants may seek to introduce such information in the course of their defense.

While the facts of this treatment are relevant and admissible, it would not be proper to disclose the identities of any patients or victims, or to refer to evidence that would potentially reveal individually identifiable health information. Federal and state statutes zealously guard the identities of children who have received services relating to abuse and neglect,<sup>25</sup> and the privacy of personal,

---

Occasionally, Plaintiffs were ordered to produce documents “emergently” at the direction of Special Master Cohen. Although some of these documents disclosed the identities of these individuals, in order to expedite production in accordance with the Special Master’s instructions, Plaintiffs did not redact the names prior to producing the documents to Defendants. To the extent Defendants seek to admit one or more of these documents, Defendants should be required to redact any identifying information for the reasons discussed herein.

<sup>25</sup> See, e.g., The Child Abuse Prevention and Treatment Act, 42 U.S.C. § 5106a(b)(2)(B)(viii) (requiring states to adopt programs “to preserve the confidentiality of all records in order to protect the rights of the child and of the child’s parents or guardians.”); The Comprehensive Alcohol Abuse and Alcoholism Prevention Treatment and Rehabilitation Act, 42 U.S.C. § 290dd; The Family Educational Rights and Privacy Act Regulations, 34 C.F.R. § 99.31; OHIO REV. CODE (“ORC”) § 5153.17 (ordering that the records of public children services agencies shall be kept confidential); ORC § 2151.421(I)(1) (noting “a report [related to child abuse or neglect] made under this section is confidential[.]”); ORC § 2151.421(L)(2) (noting “the agency shall not disclose any confidential information regarding the child who is the subject of the report”); OHIO ADMIN. CODE (“OAC”) 5101:2-33-21 (ordering that “[e]ach referral, assessment/investigation and provision of services related to reports of child abuse, neglect, dependency, or family in need of services (FINS) is confidential” and that child welfare contained in SACWIS is “confidential pursuant to section 5101.131 of the Revised Code”); ORC § 5101.131; OAC 5101:2-33-23 (providing that “[a]ll case records prepared, maintained, and permanently kept by the PCSA are confidential”); ORC § 5101.29(D) (noting records not subject to public records law); ORC § 2151.142 (mandating that “residential addresses [] contained in public records kept by a public children services agency, private child placing agency, juvenile court, or law enforcement agency [shall not be] subject to inspection or copying as part of a public record” and are confidential); OAC 5101:2-33-21(E) (providing that “[t]he PCSA shall not release the identities of the referent/reporter, and any person providing [child welfare] information during the course of an assessment/investigation shall remain confidential. The identities of these individuals shall not be released or affirmed by the PCSA to any party without the written consent of the individual(s) involved, except to those individuals outlined in paragraph (F) of this rule.”); ORC § 3107.17 (requiring the confidentiality of records related to adoption); and OAC 5101:2-48-23 (describing how after an adoption is final, an adoptive child case record is marked “confidential and permanently secure such record from release or inspection of any information, except under the following conditions . . .”).

identifiable medical information.<sup>26</sup> Throughout this action, the Court has struck a delicate balance with respect to protecting the rights of non-party citizens whose records have been produced in this action. In its April 10, 2019 “Order re Objections to Discovery Ruling No. 17,” the Court found that “de-identified SACWIS data—which will not reveal identifying information about the minors or their families but will indicate whether opiate or other drug use was a relevant factor—appropriately maintains the data’s confidentiality” and that SACWIS data “shall be redacted to protect the identities of individuals in the data.” Dkt. #1535 at pp. 3-5. The Court’s March 7, 2019 “Order Governing Production of Medical and Pharmacy Claims Data in Track One Cases” limited disclosure of the medical history produced to counsel, experts and court personnel, and affirmed prior restrictions preventing Defendants from using the data to conduct third party discovery. Dkt. #1421 at ¶¶ 4 & 8.

If medical records or similar documents are used at trial, all individually identifiable health information should be redacted, and Defendants should be precluded from referring to or mentioning any individually identifiable health information. The Health Insurance Portability and Accountability Act (HIPAA) requires removal of data that could be used to identify an individual, including names, addresses, dates of birth, telephone numbers, social security numbers, and other information. *See* 45 C.F.R. Subpart E § 164.514(b)(2)(i)(A-R).

In addition to violating the HIPAA statute, there would be no justification for introducing into evidence specific individually identifiable health information in this trial. Again, while the fact of treatment and information regarding the need for treatment by emergency personnel or healthcare providers, or the provision of other governmental services necessary to address consequences of the opioid crisis, are relevant and admissible, individually identifiable health information contained within any documents related to such treatment is *not* relevant. Plaintiffs may

---

<sup>26</sup> *See, e.g.*, The Health Insurance Portability and Accountability Act (“HIPAA”), *see* 45 C.F.R. Subpart E § 164.502 (prohibition against disclosing individually identifiable health information); 45 C.F.R. Subpart E § 164.514 (requirements for de-identification of protected health information); 42 C.F.R. Part 2 (confidentiality for records relating to treatment for substance abuse disorders).

also seek to introduce aggregate evidence relating to the impact on their communities and the need for and cost related to abatement, and that evidence may include certain statistical information.

However, any such evidence should comply with the HIPAA requirement:

Standard: De-identification of protected health information. Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

45 C.F.R. Subpart E § 164.514(a).

**27. Any reference to, or evidence of, the identity of any undercover law enforcement personnel who may be called to testify at trial.**

Defendants have included in their list of potential witnesses one or more undercover law enforcement officers who have been deposed in this litigation. If the Court admits deposition testimony from any of these witnesses at trial, Plaintiffs respectfully request that the Court take measures to ensure that the officer's identity is not publicly revealed.<sup>27</sup> In this regard, Plaintiffs request the following:

- a. If any undercover officer's testimony is offered, Defendants should be required to read the transcript of the officer's deposition, and not be permitted to use any portion of the audio recording.
- b. Defendants should be precluded from stating the officer's true name in connection with their testimony, but should instead be required to designate a pseudonym for each officer, and use that pseudonym throughout the witness's testimony.
- c. In order to have a complete record, Defendants can submit a document under seal that correlates the pseudonym used during trial with the true name of the witness.
- d. Defendants should also be precluded from offering any other testimony that could potentially be used to identify the officer, such as where he or she resides, a description of his or her physical appearance, or how long he or she has been with any particular law enforcement agency.

---

<sup>27</sup> When these officers' depositions were taken, Special Master Cohen permitted an audio recording of the depositions to be made, but did not allow videotaping.

These reasonable measures strike a balance between allowing the Defendants to offer evidence the Court determines is relevant and admissible, and protecting the confidential identity of the witnesses. “The state interest in maintaining the continued effectiveness of an undercover officer is an extremely substantial interest, and the trial judge . . . was amply justified in concluding this interest would be seriously prejudiced by requiring the officer to testify in an open courtroom.” *Ayala v. Speckard*, 131 F.3d 62, 72 (2d Cir. 1997). “It is clear that the State has an ‘overriding interest’ in protecting the identity of its undercover officer.” *Rodriguez v. Miller*, 537 F.3d 102, 110 (2d Cir. 2008).

The Supreme Court has noted that “trial judges retain wide latitude insofar as the Confrontation Clause is concerned to impose reasonable limits on such cross-examination based on concerns about, among other things, harassment, prejudice, confusion of the issues, the witness’ safety, or interrogation that is repetitive or only marginally relevant.” *Delaware v. Van Arsdall*, 475 U.S. 673, 679, 106 S. Ct. 1431, 1435 (1986); *see also United States v. Maso*, No. 07-10858, 2007 WL 3121986, at \*3 (11th Cir. 2007) (per curiam) (affirming district court’s decision to allow an undercover DEA agent to testify using a pseudonym, and noting that the defendant was aware of the witness’s true identity).<sup>28</sup>

There is no prejudice to Defendants, since they are aware of the true identity of the witnesses and had an opportunity to elicit testimony from them during their depositions. And whatever relevance or probative value the proffered testimony may have is not diminished by imposing these restrictions on Defendants. They would still be permitted to inform the jury that the witness is an undercover law enforcement officer, but would simply be precluded from identifying the officer by name or eliciting any other testimony that would publicly reveal the officer’s identity.

---

<sup>28</sup> Other courts have imposed additional restrictions when confidential witnesses testify live at trial, such as permitting them to wear “light disguises,” obscuring them from view while testifying, and in some instances closing the courtroom to the public but allowing a contemporaneous video feed that does not show the witness. If any Defendant calls an undercover officer to testify live at trial rather than by deposition, Plaintiffs respectfully request that they be afforded an opportunity to address the Court regarding what other measures might be necessary to protect the witness’s identity.



**28. Any reference to deaths of individuals while in the Cuyahoga County Jail or in the custody of the Cuyahoga County Sheriff's Office, and any reference to the U.S. Marshalls Service report on jails.**

Any evidence of or reference to deaths of individuals while in the Cuyahoga County Jail or in the custody of the Cuyahoga County Sheriff's Office, and any reference to the U.S. Marshalls Service report on jails, is not relevant to any issue to be decided in this case. The U.S. Marshalls Service issued a Quality Assurance Review of the Cuyahoga County Correctional Center from October 30 to November 1, 2018 which does not discuss opioids or substance abuse issues at the jail. This evidence is irrelevant, as is any reference to deaths that occurred in the jail or while an individual was in the custody of the Sheriff's Office, because this evidence is unrelated to the claims or defenses at issue in this case. Defendants' sole purpose in trying to elicit such information would be to attempt to prejudice the jury against Cuyahoga County for reasons that are unrelated to the matters at issue in this case. Such evidence should be excluded under Rules 401, 402 and 403 because it is irrelevant to the jury questions on liability and damages and any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading or inflaming the jury.

**29. Any reference to or allegation of current or former government corruption in Cuyahoga County.**

Any evidence of or reference to allegations of current or former government corruption in Cuyahoga County is not relevant to any issue to be decided in this case. Defendants' sole purpose in trying to elicit such information would be to attempt to prejudice the jury. Such evidence should be excluded under Rules 401, 402 and 403. For example, Defendants should not be allowed to argue that Cuyahoga County mismanaged their funds or did not have the money necessary to fight opioids due to corruption because such allegations would not have "any tendency to make the existence of any fact *that is of consequence to the determination of the action* more probable or less probable than it would be without the evidence." FED. R. EVID. 401 (emphasis added). Moreover, even if the allegations were relevant, which they are not, they are inadmissible under Rule 403 because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading the



jury. *See Doe v. Claiborne County*, 103 F.3d 495, 515 (6th Cir. 1996) (unfair prejudice is “the undue tendency to suggest a decision based on improper considerations”). Any alleged corruption in the Cuyahoga County government, especially when that corruption has nothing to do with opioids, is irrelevant to the jury questions on liability and damages.

**30. Any reference to grand jury testimony or proceedings involving Cuyahoga County.**

Any evidence of or reference to grand jury testimony or proceedings involving Cuyahoga County is inadmissible. Grand jury evidence is subject to strict secrecy rules. *See* FED. R. CRIM. P. 6(e). Defendants cannot show the required “particularized need” for such materials, which are unconnected to the issues in this case. *See Wilson v Sheldon*, 874 F.3d 470, 477 (6<sup>th</sup> Cir. 2017); *In re Grand Jury Proceedings*, 841 F.2d 1264, 1267-68 (6<sup>th</sup> Cir. 1988) (departure from grand jury secrecy rules can only be in cases of “compelling necessity” where there is proof that without access to the grand jury materials a litigant's position would be “greatly prejudiced” or “an injustice would be done.”). In addition, this evidence should be excluded under Rules 401, 402 and 403 because it is irrelevant to the jury questions on liability and damages and any probative value it might have is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading the jury.

**31. Any reference to recent investigations or subpoenas involving Cuyahoga County.**

Any evidence of or reference to recent investigations or subpoenas involving Cuyahoga County is not relevant to any issue to be decided in this case. Defendants’ sole purpose in trying to elicit such information would be to attempt to prejudice the jury. Such evidence should be excluded under Rules 401, 402 and 403. As discussed in MIL No. 29, recent investigations or subpoenas involving Cuyahoga County, which have nothing to do with opioids, are irrelevant to the jury questions on liability and damages.

**32. Any reference to the indictment of Ken Mills, former director of Cuyahoga County jails.**

Any reference to the indictment of Ken Mills, former director of Cuyahoga County jails, is not relevant to any issue to be decided in this case. The indictment is unrelated to opioids or substance abuse at the jail and he has not participated as a witness in this case either via written interrogatory responses or through a deposition. Any evidence on his indictment should be excluded under Rules 401, 402 and 403 because it is irrelevant to the jury questions on liability and damages and has no probative value. Any probative value this evidence might have is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading the jury.

**33. Any reference to any investigations of former Cuyahoga County Sheriff Pinkney or the Cuyahoga County Sheriff's Office.**

Any evidence of or reference to any investigations of former Cuyahoga County Sheriff Pinkney or the Cuyahoga County Sheriff's Office is not relevant to any issue to be decided in this case. Similar to the arguments in MIL Nos. 28-29, the evidence Defendants would try to submit would have nothing to do with opioids or any issue the jury must determine in this case and is thus irrelevant. Defendants' sole purpose in trying to elicit such information would be to attempt to prejudice the jury against Cuyahoga County for reasons that are unrelated to the claims or defenses in this case. Such evidence should be excluded under Rules 401, 402 and 403 because it is irrelevant to the jury questions on liability and damages and any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading or inflaming the jury.

**34. Any reference to any "podcast" or other media coverage regarding Cuyahoga County courts.**

Any evidence of or reference to any "podcast" or other media coverage regarding the Cuyahoga County courts is not relevant to any issue to be decided in this case and could inflame the jury. The evidence Defendants would try to submit would have nothing to do with opioids or any issue the jury must determine in this case and is thus irrelevant. For example, "Serial" is an investigative journalism podcast which focuses on criminal justice, with its most recent season centered on the courts and criminal justice system in Cleveland. See <https://serialpodcast.org/>. The

focus of the series was not on opioids or substance abuse. It, along with any other media coverage regarding the Cuyahoga County courts, is not relevant to any claim or defense in this case. Defendants' sole purpose in referring to such information would be to attempt to prejudice the jury against Cuyahoga County. This evidence should be excluded under Rules 401, 402 and 403 because it is irrelevant to the jury questions on liability and damages and has no probative value. Any probative value this evidence might have is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading or inflaming the jury.

**35. Any reference to any investigation regarding the death of Aniya Day Garrett.**

Any reference to any investigation regarding the death of Aniya Day Garrett is not relevant to any issue to be decided in this case and could inflame or mislead the jury. Aniya Day Garrett was a four year old girl who died in March 2018. Her mother and the mother's boyfriend were found guilty of her murder. There were no allegations or findings that opioids or drug abuse were in any way related to her death. This evidence should be excluded under Rules 401, 402 and 403 because it is irrelevant to the jury questions on liability and damages and has no probative value. Any probative value this evidence might have is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading or inflaming the jury.

**36. Any reference to or allegation of current or former government corruption in Summit County.**

Any evidence of or reference to allegations of current or former government corruption in Summit County is not relevant to any issue to be decided in this case. Defendants' sole purpose in trying to elicit such information would be to attempt to prejudice the jury. Such evidence should be excluded under Rules 401, 402 and 403. Any evidence or argument concerning any Summit County officials or former officials has nothing to do with opioids and would be irrelevant and distracting. Moreover, even if the allegations were relevant, which they are not, they are inadmissible under Rule 403 because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading the jury. *See Doe*, 103 F.3d at 515 (unfair prejudice is "the undue

tendency to suggest a decision based on improper considerations”). Any alleged corruption in the Summit County government, especially when that corruption has nothing to do with opioids, is irrelevant to the jury questions on liability and damages.

**37. Any reference to deaths of individuals while in the Summit County Jail or in the custody of the Summit County Sheriff’s Office.**

Any evidence of or reference to deaths of individuals while in the Summit County Jail or in the custody of the Summit County Sheriff’s Office should be excluded. Any such evidence or argument is unrelated to the claims or defenses at issue in this case. Defendants’ sole purpose in trying to elicit such information would be to attempt to prejudice the jury against Summit County for reasons that are unrelated to the matters at issue in this case. Such evidence should be excluded under Rules 401, 402 and 403 because it is irrelevant to the jury questions on liability and damages and any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading or inflaming the jury.

Dated: September 25, 2019

Respectfully submitted,

/s/Paul J. Hanly, Jr.

Paul J. Hanly, Jr.

SIMMONS HANLY CONROY

112 Madison Avenue, 7<sup>th</sup> Floor

New York, NY 10016

(212) 784-6400

(212) 213-5949 (fax)

[phanly@simmonsfirm.com](mailto:phanly@simmonsfirm.com)

Joseph F. Rice

MOTLEY RICE

28 Bridgeside Blvd.

Mt. Pleasant, SC 29464

(843) 216-9000

(843) 216-9290 (Fax)

[jrice@motleyrice.com](mailto:jrice@motleyrice.com)

Paul T. Farrell, Jr., Esq.  
GREENE KETCHUM, LLP  
419 Eleventh Street  
Huntington, WV 25701  
(304) 525-9115  
(800) 479-0053  
(304) 529-3284 (Fax)  
paul@greeneketchum.com

*Plaintiffs' Co-Lead Counsel*

/s/ Peter H. Weinberger  
Peter H. Weinberger (0022076)  
SPANGENBERG SHIBLEY & LIBER  
1001 Lakeside Avenue East, Suite 1700  
Cleveland, OH 44114  
(216) 696-3232  
(216) 696-3924 (Fax)  
pweinberger@spanglaw.com

*Plaintiffs' Liaison Counsel*

W. Mark Lanier  
THE LANIER LAW FIRM  
6810 FM 1960 Rd W  
Houston, TX 77069-3804  
(713) 659-5200  
(713) 659-2204 (Fax)  
[wml@lanierlawfirm.com](mailto:wml@lanierlawfirm.com)

*Lead Trial Counsel*

Hunter J. Shkolnik  
NAPOLI SHKOLNIK  
360 Lexington Ave., 11<sup>th</sup> Floor  
New York, NY 10017  
(212) 397-1000  
(646) 843-7603 (Fax)  
hunter@napolilaw.com

*Counsel for Plaintiff Cuyahoga County, Ohio*

Linda Singer  
MOTLEY RICE LLC  
401 9th St. NW, Suite 1001  
Washington, DC 20004  
(202) 386-9626 x5626  
(202) 386-9622 (Fax)  
lsinger@motleyrice.com

*Counsel for Plaintiff Summit County, Ohio*

**CERTIFICATE OF SERVICE**

I certify that the foregoing instrument was served via the Court's ECF system to all counsel of record on September 25, 2019.

/s/ Andrea Bierstein  
Andrea Bierstein